

## EXHIBIT 92

1 UNITED STATES DISTRICT COURT  
2 FOR THE NORTHERN DISTRICT OF OHIO  
3 EASTERN DIVISION

4 \*\*\*\*\*

5 IN RE: NATIONAL MDL No. 2804  
6 PRESCRIPTION OPIATE  
7 LITIGATION Case No.  
8 1:17-MD-2804

9 \*\*\*\*\*

10 THIS DOCUMENT RELATES TO Hon. Dan A. Polster  
11 ALL CASES

12 \*\*\*\*\*

13 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER  
14 CONFIDENTIALITY REVIEW  
15 VIDEOTAPED DEPOSITION OF EILEEN SPAULDING

16 Tuesday, February 5th, 2019  
17 9:06 a.m.

18 Held At:  
19 Ropes & Gray LLP  
20 800 Boylston Street  
21 Boston, Massachusetts

22  
23 REPORTED BY:  
24 Maureen O'Connor Pollard, RMR, CLR, CSR

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<p style="text-align: right;">Page 10</p> <p>1 PROCEEDINGS</p> <p>2</p> <p>3 THE VIDEOGRAPHER: We are now on the</p> <p>4 record. My name is Robert Martignetti, I'm a</p> <p>5 videographer for Golkow Litigation Services.</p> <p>6 Today's date is February 5, 2019, and the time</p> <p>7 is 9:06 a.m.</p> <p>8 This video deposition is being held in</p> <p>9 Boston, Massachusetts, In Re: National Opiate</p> <p>10 Litigation.</p> <p>11 The deponent is Eileen Spaulding.</p> <p>12 Counsel will be noted on the</p> <p>13 stenographic record.</p> <p>14 The court reporter is Maureen Pollard,</p> <p>15 and will now swear in the witness.</p> <p>16</p> <p>17 EILEEN SPAULDING,</p> <p>18 having been duly identified and sworn, was</p> <p>19 examined and testified as follows:</p> <p>20 EXAMINATION</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. Good morning, Ms. Spaulding.</p> <p>23 A. Good morning.</p> <p>24 Q. My name is Gary Gotto. We met briefly</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. I'm pretty sure we can all be heard.</p> <p>2 We will take breaks periodically</p> <p>3 today, but if you need a break at any point, as</p> <p>4 long as there's not a question pending, just let</p> <p>5 me know, and we'll accommodate that. Okay?</p> <p>6 A. Okay.</p> <p>7 Q. By whom are you employed?</p> <p>8 A. Mallinckrodt.</p> <p>9 Q. And what's your business address?</p> <p>10 A. 172 Railroad Avenue, Hobart, New York</p> <p>11 13788.</p> <p>12 Q. And when did you first become employed</p> <p>13 at Mallinckrodt?</p> <p>14 A. December of 1998.</p> <p>15 Q. Before we get into your Mallinckrodt</p> <p>16 employment, just a little bit of background.</p> <p>17 Describe for me briefly your post-high school</p> <p>18 education.</p> <p>19 A. So I have an associate's in computer</p> <p>20 information systems technology from BYU. And I</p> <p>21 went into the workforce for Elastic Stop Nut for</p> <p>22 approximately two years after graduation. I</p> <p>23 then worked for J.L. Hammett School Supplies as</p> <p>24 a customer service rep for ten years, PSE&amp;G as a</p>
<p style="text-align: right;">Page 11</p> <p>1 just before we went on the record. We've never</p> <p>2 met before today, correct?</p> <p>3 A. Correct.</p> <p>4 Q. Have you ever given a deposition</p> <p>5 previously?</p> <p>6 A. No.</p> <p>7 Q. Okay. Well, we will -- just a few</p> <p>8 items by way of background. Please let me</p> <p>9 finish my questions if you can, and I'll</p> <p>10 certainly try to let you finish your answers</p> <p>11 before so we don't speak over each other.</p> <p>12 If any of my questions are unclear to</p> <p>13 you in any way, let me know and I'll do my best</p> <p>14 to clarify them.</p> <p>15 A. Okay.</p> <p>16 Q. If you answer a question without</p> <p>17 asking for a clarification, I'll assume you felt</p> <p>18 like you understood it. Okay?</p> <p>19 A. Yes.</p> <p>20 Q. And this is kind of a large table so</p> <p>21 I'll try to keep my voice up so we can all hear</p> <p>22 each other. But I'm not shouting, I'm just</p> <p>23 trying to --</p> <p>24 A. I understand.</p>	<p style="text-align: right;">Page 13</p> <p>1 customer service rep for approximately two</p> <p>2 years, and then I relocated to New York and</p> <p>3 started with Mallinckrodt.</p> <p>4 Q. Okay. What is PSE&amp;G?</p> <p>5 A. Public Service Electric &amp; Gas. It's</p> <p>6 the electric company for the State of New</p> <p>7 Jersey.</p> <p>8 Q. Okay. And do you hold any</p> <p>9 professional licenses or certifications?</p> <p>10 A. No.</p> <p>11 Q. Approximately when did you get your</p> <p>12 associate's degree?</p> <p>13 A. I graduated in 1990.</p> <p>14 Q. Okay. All right. And prior to</p> <p>15 Mallinckrodt did you have any employment history</p> <p>16 that was related in any way to the</p> <p>17 pharmaceuticals industry?</p> <p>18 A. No.</p> <p>19 Q. In your undergraduate work did you</p> <p>20 take any coursework that related to the</p> <p>21 pharmaceuticals industry?</p> <p>22 A. No.</p> <p>23 Q. Have you done any other formal --</p> <p>24 apart from on-the-job training or internal</p>

<p style="text-align: right;">Page 14</p> <p>1 training programs provided at Mallinckrodt, any</p> <p>2 other educational programs that you've taken</p> <p>3 that relate in any way to the pharmaceuticals</p> <p>4 industry?</p> <p>5 A. Not sure I understand what you mean.</p> <p>6 Like DEA training seminars?</p> <p>7 Q. That would be -- let me -- the</p> <p>8 pharmaceuticals industry -- well, let's be as</p> <p>9 broad as we can. That relate to pharmaceuticals</p> <p>10 in any way, so that would include anything</p> <p>11 related to DEA training or the Controlled</p> <p>12 Substances Act, anything of that nature.</p> <p>13 A. Yes. So I've attended several DEA</p> <p>14 pharmaceutical training seminars sponsored by</p> <p>15 the DEA; pharmaceutical industry conferences</p> <p>16 also sponsored by DEA; HDMA, which is now known</p> <p>17 as HDA, two of their conferences; and</p> <p>18 BuzzeePDMA, now IQVIA, I've attended multiple</p> <p>19 industry conferences.</p> <p>20 Q. Okay. And have those all been during</p> <p>21 the time you were employed by Mallinckrodt?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. We'll get into that in just a</p> <p>24 bit.</p>	<p style="text-align: right;">Page 16</p> <p>1 A. Yes.</p> <p>2 Q. And did any of those documents refresh</p> <p>3 your recollection in any regard?</p> <p>4 A. Yes.</p> <p>5 Q. And in what regards can you recall</p> <p>6 your recollection being refreshed?</p> <p>7 A. Well, once I'd read the e-mail, then</p> <p>8 it would remind me of what the topic or the</p> <p>9 subject matter was.</p> <p>10 Q. Okay. Was there any particular matter</p> <p>11 you can recall reviewing a document and having</p> <p>12 that document refresh your recollection as to a</p> <p>13 specific subject matter or event?</p> <p>14 MR. O'CONNOR: I'm going to object,</p> <p>15 and instruct the witness not to answer to the</p> <p>16 extent it would get into which particular</p> <p>17 documents we were looking at which would be</p> <p>18 protected by the attorney/client communication</p> <p>19 privilege and work product doctrine.</p> <p>20 BY MR. GOTTO:</p> <p>21 Q. So again, and I think this is</p> <p>22 consistent with your counsel's instruction, I'd</p> <p>23 like you to tell me not the document itself but</p> <p>24 just the subject matter, what the event or the</p>
<p style="text-align: right;">Page 15</p> <p>1 Tell me what you did -- and I don't</p> <p>2 want you to disclose any communications with</p> <p>3 your counsel, but what did you do to prepare for</p> <p>4 today's deposition?</p> <p>5 A. I met with my counsel.</p> <p>6 Q. Okay. And how many times did you meet</p> <p>7 with counsel?</p> <p>8 A. Three.</p> <p>9 Q. And approximately when did you meet</p> <p>10 with counsel?</p> <p>11 A. Two in January, and one yesterday.</p> <p>12 Q. And were those personal meetings or</p> <p>13 telephonic?</p> <p>14 A. Personal.</p> <p>15 Q. And who was present?</p> <p>16 A. Kate and Andrew.</p> <p>17 Q. No one else?</p> <p>18 A. No.</p> <p>19 Q. Approximately how long did each one of</p> <p>20 the meetings last?</p> <p>21 A. Seven to eight hours.</p> <p>22 Q. And you can just answer this yes or</p> <p>23 no. Did you review any documents during those</p> <p>24 meetings?</p>	<p style="text-align: right;">Page 17</p> <p>1 subject matter as to which you can recall your</p> <p>2 recollection being refreshed by reviewing a</p> <p>3 document.</p> <p>4 MR. O'CONNOR: You can answer at a</p> <p>5 general level.</p> <p>6 A. Whatever the subject was of the</p> <p>7 particular document I would remember upon</p> <p>8 reading it.</p> <p>9 BY MR. GOTTO:</p> <p>10 Q. Sure. Okay.</p> <p>11 Fair to say, then, there's not a</p> <p>12 specific thing that comes to your mind as you're</p> <p>13 sitting here today of, for example, reviewing a</p> <p>14 document and having the sensation of oh, gee, I</p> <p>15 forgot all about that meeting but now that I</p> <p>16 review this document I remember there was such a</p> <p>17 meeting, or anything of that nature that would</p> <p>18 be more specific than just a general, well, I</p> <p>19 see a document and that at some level, you know,</p> <p>20 causes me to better remember something that</p> <p>21 happened some years back?</p> <p>22 A. No.</p> <p>23 Q. Okay. Have you reviewed any</p> <p>24 transcripts of any deposition testimony given by</p>



<p style="text-align: right;">Page 18</p> <p>1 any of the witnesses in this matter?</p> <p>2 A. No.</p> <p>3 Q. Have you had -- well, have you spoken</p> <p>4 to anyone who has given a deposition in this</p> <p>5 matter with respect to their deposition?</p> <p>6 A. Only that they had been deposed.</p> <p>7 Nothing of the subject matter.</p> <p>8 Q. Okay. And who did you speak to in</p> <p>9 that regard?</p> <p>10 A. Karen Harper.</p> <p>11 Q. Anyone else?</p> <p>12 A. No.</p> <p>13 Q. Have you reviewed any of the papers</p> <p>14 that have been filed in court related to this</p> <p>15 litigation, including any of the complaints</p> <p>16 filed by any of the plaintiffs?</p> <p>17 A. No.</p> <p>18 Q. Are you aware that there's in excess</p> <p>19 of a thousand complaints that have been filed by</p> <p>20 various governmental entities, counties,</p> <p>21 municipalities, etcetera, relating to the opioid</p> <p>22 epidemic?</p> <p>23 A. Yes.</p> <p>24 Q. And again without divulging any</p>	<p style="text-align: right;">Page 20</p> <p>1 Okay. Do you have at home any paper</p> <p>2 files that in any way relate to your work at</p> <p>3 Mallinckrodt?</p> <p>4 A. No.</p> <p>5 Q. And have you at any time?</p> <p>6 A. No. I apologize, I step back. I have</p> <p>7 taken work home previously to complete and bring</p> <p>8 back to work the next day.</p> <p>9 Q. Okay. But in terms of maintaining a</p> <p>10 file in a file --</p> <p>11 A. No, absolutely --</p> <p>12 Q. -- cabinet at your home or anything</p> <p>13 like that, that's not something that you do?</p> <p>14 A. No, absolutely not.</p> <p>15 Q. Okay. Well, let's talk about your</p> <p>16 employment at Mallinckrodt. I'd like first to</p> <p>17 just get a general sense of the positions that</p> <p>18 you've held over the years. I realize you've</p> <p>19 been there a long time and you may be a little</p> <p>20 fuzzy on particular dates, and that's fine.</p> <p>21 This isn't a memory contest. And we'll look at</p> <p>22 some documents that may pin down some dates from</p> <p>23 time to time as we go through today.</p> <p>24 But just at a general level, if you</p>
<p style="text-align: right;">Page 19</p> <p>1 communications with counsel, how did you first</p> <p>2 become aware of that?</p> <p>3 A. It's only through counsel that I am</p> <p>4 aware of that.</p> <p>5 Q. Is it a subject -- the litigation, is</p> <p>6 that a subject that you've had any conversations</p> <p>7 with anyone else at Mallinckrodt, again apart</p> <p>8 from communications with counsel?</p> <p>9 A. No.</p> <p>10 Q. Have you taken any steps to preserve</p> <p>11 any documents that might in any way relate to</p> <p>12 the subject matter of the opioid litigation?</p> <p>13 A. So we have a document preservation</p> <p>14 notice that's been issued, so all documents have</p> <p>15 been preserved.</p> <p>16 Q. Okay. But -- and that would apply to</p> <p>17 documents that, for example, are on Mallinckrodt</p> <p>18 servers or on your work computer, that sort of</p> <p>19 thing?</p> <p>20 A. I can only speak to my work computer.</p> <p>21 Q. Okay. In terms of -- do you have a</p> <p>22 personal computer at home?</p> <p>23 A. Actually, no, I don't.</p> <p>24 Q. You don't.</p>	<p style="text-align: right;">Page 21</p> <p>1 can tell me the positions that you've held over</p> <p>2 the years at Mallinckrodt.</p> <p>3 A. Sure. I started in their packaging</p> <p>4 department as a packaging operator in 1998. I</p> <p>5 was in that department for approximately a year</p> <p>6 and a half, and I transitioned into the</p> <p>7 validations department. And I was with</p> <p>8 validations for approximately two years. And</p> <p>9 then in April of 2001, I transitioned into the</p> <p>10 compliance role.</p> <p>11 Q. Okay. So prior to April of '01, in</p> <p>12 the packaging and validations positions, just</p> <p>13 tell me generally what responsibilities you had</p> <p>14 in those positions.</p> <p>15 A. In packaging it was working on the</p> <p>16 line that puts the tablets and capsules into the</p> <p>17 bottles, running the machinery.</p> <p>18 And then in validations it was</p> <p>19 executing protocols and taking samples to</p> <p>20 validate products for FDA approval.</p> <p>21 Q. Okay. And did you receive any</p> <p>22 training with respect to either of those</p> <p>23 positions?</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 22</p> <p>1 Q. What was the nature of the training?</p> <p>2 A. So in packaging would have been</p> <p>3 on-the-job training, classroom training, SOP</p> <p>4 training.</p> <p>5 The same for validations.</p> <p>6 Validations, I had in the beginning a one-on-one</p> <p>7 trainer that would show me how to take samples</p> <p>8 and execute the protocols, how to write reports.</p> <p>9 Q. And what is SOP training?</p> <p>10 A. Reading SOPs, standard operating</p> <p>11 procedures. We have a computer system that</p> <p>12 assigns us SOPs based on our curriculum, and we</p> <p>13 read those, and in some cases take -- there's a</p> <p>14 quiz associated with those SOPs.</p> <p>15 Q. Okay. You said April of '01 you</p> <p>16 transitioned to a compliance role. What was the</p> <p>17 compliance role that you transitioned into?</p> <p>18 A. So in April of 2001, the reason I</p> <p>19 remember the date is because that's when our</p> <p>20 distribution center opened, and a newly created</p> <p>21 position of compliance investigator -- excuse</p> <p>22 me, compliance investigator was created in which</p> <p>23 I did the ARCOS reporting. I would investigate</p> <p>24 any losses in transit with the carriers, made</p>	<p style="text-align: right;">Page 24</p> <p>1 manufacturers on behalf of Mallinckrodt.</p> <p>2 Q. So prior to having the distributor</p> <p>3 license, Mallinckrodt had a license to</p> <p>4 manufacture controlled substances, correct?</p> <p>5 A. Yes.</p> <p>6 Q. And so it would then -- what would it</p> <p>7 then do with the controlled substances after it</p> <p>8 manufactured them?</p> <p>9 A. It would send them to St. Louis for</p> <p>10 distribution.</p> <p>11 Q. And did Mallinckrodt in St. Louis have</p> <p>12 a distribution license?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. So the distributor license that</p> <p>15 was obtained in '01 was for the Hobart facility?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. So when you took the position</p> <p>18 of compliance investigator, to whom did you</p> <p>19 report at that time?</p> <p>20 A. Liz McPhail.</p> <p>21 Q. And what was her position?</p> <p>22 A. Purchasing manager.</p> <p>23 Q. And for how long did that reporting</p> <p>24 relationship continue?</p>
<p style="text-align: right;">Page 23</p> <p>1 sure our reports were filed on time, handled</p> <p>2 destruction of the pharmaceutical waste, and any</p> <p>3 other tasks as assigned.</p> <p>4 Q. Okay. And you indicated this was a</p> <p>5 new position that was created in '01, is that</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. And it was related to the</p> <p>9 establishment of the distribution center?</p> <p>10 A. Yes, it was an additional license that</p> <p>11 was started at the Hobart site.</p> <p>12 Q. And what was the nature of the</p> <p>13 additional license?</p> <p>14 A. A distribution center. So previous to</p> <p>15 that we had only had a manufacturing DEA license</p> <p>16 and an analytical license. The addition of the</p> <p>17 distribution center in Hobart created the need</p> <p>18 to have a DEA distributor license and a DEA</p> <p>19 exporter license.</p> <p>20 Q. And so the DEA distributor license,</p> <p>21 what did that permit Mallinckrodt to do that it</p> <p>22 hadn't done previously?</p> <p>23 A. To distribute either Mallinckrodt-made</p> <p>24 products or products that were made by other</p>	<p style="text-align: right;">Page 25</p> <p>1 A. I don't recall exactly.</p> <p>2 Q. Was it some number of years?</p> <p>3 A. A few years.</p> <p>4 Q. Okay. And to whom did you report</p> <p>5 after you no longer reported to Ms. McPhail?</p> <p>6 A. To the materials manager.</p> <p>7 Q. And who was that?</p> <p>8 A. Tim Bach, and then later Aaron</p> <p>9 Nikolaus.</p> <p>10 Q. And for how long did those reporting</p> <p>11 relationships continue?</p> <p>12 A. Again, a few years.</p> <p>13 Q. And after that to whom did you report?</p> <p>14 A. Karen Harper.</p> <p>15 Q. Do you recall approximately when you</p> <p>16 began reporting to Ms. Harper?</p> <p>17 A. 2008 sometime.</p> <p>18 Q. And do you recall what her position</p> <p>19 was at that time?</p> <p>20 A. Senior manager of controlled</p> <p>21 substances compliance.</p> <p>22 Q. And for how long did your reporting</p> <p>23 relationship with Ms. Harper continue?</p> <p>24 A. I'm still reporting to Karen Harper.</p>



<p style="text-align: right;">Page 26</p> <p>1 Q. Okay. The position compliance</p> <p>2 investigator which you indicated was a new</p> <p>3 position when you took it in '01, did you</p> <p>4 receive a written job description or a list of</p> <p>5 responsibilities?</p> <p>6 A. I don't remember.</p> <p>7 Q. How did you come to have that</p> <p>8 position? Did you apply for it?</p> <p>9 A. Yes. There was a posting internally</p> <p>10 which I applied and was interviewed and awarded</p> <p>11 the position.</p> <p>12 Q. Do you recall by whom you were</p> <p>13 interviewed?</p> <p>14 A. Liz McPhail was one of them. I don't</p> <p>15 remember who the others were.</p> <p>16 Q. And did you have an understanding at</p> <p>17 the time as to what in your background qualified</p> <p>18 you for that position?</p> <p>19 A. I guess just being an operator and</p> <p>20 familiar with our processes and our products.</p> <p>21 Q. And you listed a few items that you</p> <p>22 had responsibility for, for example, ARCOS</p> <p>23 reporting. What was ARCOS reporting?</p> <p>24 A. ARCOS reporting is -- at that time we</p>	<p style="text-align: right;">Page 28</p> <p>1 tell me at the beginning how you did it, and</p> <p>2 then how that process changed over the years.</p> <p>3 A. So at the beginning it was a --</p> <p>4 basically a -- we call it DDS, dangerous drug</p> <p>5 system, would compile all of the data for the</p> <p>6 receipts, and the shipments, and download it</p> <p>7 into ARCOS format, which is -- I don't know,</p> <p>8 it's a specific format, and then we would</p> <p>9 download it onto disk and mail that disk to DEA</p> <p>10 quarterly. Over time we started reporting</p> <p>11 monthly at the request of DEA. And then in time</p> <p>12 DEA had enhanced their systems to be able to</p> <p>13 report online.</p> <p>14 So now we have two computer systems</p> <p>15 that we merged together, our manufacturing and</p> <p>16 our distribution center inventory systems, we</p> <p>17 merged those together into a file that converts</p> <p>18 to ARCOS format, and we upload it via a portal</p> <p>19 on a monthly basis.</p> <p>20 Q. Okay. When did it -- did the reports</p> <p>21 convert from quarterly to monthly, if you</p> <p>22 remember?</p> <p>23 A. I don't remember exactly when.</p> <p>24 Q. Is there anyone else involved in the</p>
<p style="text-align: right;">Page 27</p> <p>1 were reporting quarterly all of our</p> <p>2 distributions to our next downstream direct</p> <p>3 customer.</p> <p>4 Q. And those reports went to whom?</p> <p>5 A. DEA.</p> <p>6 Q. Okay. And so was it your -- you had</p> <p>7 responsibility for completing those reports, is</p> <p>8 that right?</p> <p>9 A. For the distributor license.</p> <p>10 Q. And do you continue to have that</p> <p>11 responsibility today?</p> <p>12 A. Yes.</p> <p>13 Q. Tell me what the -- just in general</p> <p>14 what the ARCOS report reports to the DEA?</p> <p>15 A. So ARCOS is Automation Reports</p> <p>16 Consolidated Ordering System, and it is all of</p> <p>17 our receipts, so any product that we bring in we</p> <p>18 record and any product we ship out we record,</p> <p>19 and so it's acquisitions and dispositions.</p> <p>20 Q. And how do you go about gathering the</p> <p>21 data that you include in that report?</p> <p>22 A. For what time period? Because it's</p> <p>23 changed.</p> <p>24 Q. Okay. Fair enough. Maybe you can</p>	<p style="text-align: right;">Page 29</p> <p>1 process of compiling the data and transmitting</p> <p>2 the ARCOS reports?</p> <p>3 A. For which DEA license?</p> <p>4 Q. Well, are you involved in the ARCOS</p> <p>5 reporting for other than the Hobart distribution</p> <p>6 license?</p> <p>7 A. Now I am. Back at the beginning of my</p> <p>8 role I was not. Now, as manager, there's</p> <p>9 another person that works under me, and she does</p> <p>10 the manufacturing DEA ARCOS, and I do the</p> <p>11 distributor ARCOS.</p> <p>12 Q. Okay.</p> <p>13 A. And we're backup for each other.</p> <p>14 Q. Okay. And when did that come to be</p> <p>15 that you had someone working under you that you</p> <p>16 just described?</p> <p>17 A. In April of 2017.</p> <p>18 Q. So prior to the time that you had this</p> <p>19 person working under you on the manufacturing</p> <p>20 license, was there anyone else involved in</p> <p>21 compiling or transmitting the ARCOS reports that</p> <p>22 you had responsibility for?</p> <p>23 A. No.</p> <p>24 Q. Was there any process in place to</p>

<p style="text-align: right;">Page 30</p> <p>1 review the ARCOS reports that you prepared for          2 accuracy or completeness?          3 MR. O'CONNOR: Object to form.          4 A. I'm not sure I understand. It's a          5 computer download.          6 BY MR. GOTTO:          7 Q. Okay. So let's go back to when it was          8 a physical report that you were preparing and          9 sending to the DEA. There was an actual paper          10 report at some point, correct?          11 A. No, it was a file that we just put          12 onto a disk. But ARCOS requires it in a          13 specific format, and it's not human readable.          14 It's a number of fields all pressed together.          15 Q. Okay. So you would input the data          16 into that format, is that how it would be          17 prepared?          18 A. It would -- we have a computer program          19 that downloads it into that format.          20 Q. And so your personal involvement in          21 the preparation of the reports, what does it          22 consist of?          23 A. Executing those -- a series of steps          24 that allows the computer to pull down the sales</p>	<p style="text-align: right;">Page 32</p> <p>1 A. Both, you know, that the reports were          2 filed on time.          3 Q. Okay. And other than timeliness, any          4 other aspect of the reporting that was subject          5 of any goals or reviews?          6 A. Not that I can recall.          7 Q. Do you have an understanding of the          8 purpose of the -- from the DEA's standpoint, do          9 you have an understanding of the purpose for the          10 ARCOS reports?          11 MR. O'CONNOR: Objection to form.          12 A. At a very high level.          13 BY MR. GOTTO:          14 Q. And what's that understanding?          15 A. Is that it reports all of the          16 acquisitions and distributions. My ARCOS report          17 tells DEA everything we've acquired and          18 everything we've distributed. And then if          19 there's error reports, DEA will send us -- after          20 we file the report, DEA sends us an error          21 report, and if there's errors in the ARCOS data,          22 then we fix those errors on the next quarterly          23 report, or now monthly report.          24 Q. And does that happen regularly, that</p>
<p style="text-align: right;">Page 31</p> <p>1 data and convert it to ARCOS format, and then if          2 there's any manual transactions or errors or          3 returns, I would enter those into the computer          4 system which would download into that ARCOS          5 format.          6 Q. Okay. So, and is that a description          7 that's still current?          8 A. Yes.          9 Q. Okay.          10 A. And it's the same for both DEA          11 licenses.          12 Q. Okay. So is there any process in          13 place at Mallinckrodt, or has there been at any          14 point, to review any of the steps that you take          15 that you just described for accuracy, errors,          16 completeness, etcetera?          17 MR. O'CONNOR: Object to form.          18 A. Not that I'm aware of.          19 BY MR. GOTTO:          20 Q. Okay. Is the ARCOS reporting function          21 something that is a subject of any annual goals          22 that you set or reviews that you receive?          23 A. It was earlier in my career.          24 Q. Okay. Goals or reviews or both?</p>	<p style="text-align: right;">Page 33</p> <p>1 there are errors?          2 A. Not regularly, but on occasion.          3 Q. And what's the nature of the errors          4 typically?          5 A. If there's a keypunch of a wrong digit          6 and a wrong character that the system has          7 downloaded, or if a DEA number has been -- was          8 missed.          9 Q. Okay. And the nature of the          10 information that you submit in the ARCOS report,          11 you indicated it's -- what you acquired and what          12 you distributed, at what level of detail is that          13 information? Is it by, for example, API, or how          14 is it categorized?          15 MR. O'CONNOR: Object to form.          16 A. For which license?          17 BY MR. GOTTO:          18 Q. The distributor license.          19 A. So it's by finished goods, SKU, so the          20 individual number of bottles, packaged unit, and          21 so the number of bottles received and number of          22 bottles shipped, if there was any returns from a          23 customer for any reason, or if there's been any          24 waste, scrap.</p>

<p style="text-align: right;">Page 34</p> <p>1 Q. Okay. And the bottles received in the  2 case of the Hobart facility, from whom would  3 they be received?</p> <p>4 A. They could be received from the Hobart  5 manufacturing facility, or from an external  6 manufacturer.</p> <p>7 Q. Okay. And so that manufacturer,  8 whether it's Mallinckrodt Hobart or another  9 manufacturer, they would be reporting on a  10 separate ARCOS report their receipt and then  11 sale of those manufactured goods, correct?</p> <p>12 A. Yes. Correct.</p> <p>13 Q. And that's not a process you're  14 involved in in the Hobart facility, correct, or  15 at least until April, 2001 -- 2017, you were not  16 involved in that process?</p> <p>17 MR. O'CONNOR: Object to form.</p> <p>18 A. No, I misunderstand.</p> <p>19 BY MR. GOTTO:</p> <p>20 Q. The process I'm referring to is  21 whatever ARCOS report related to Hobart's  22 manufacturing activities, that report is not  23 something that at least until April of 2017 you  24 had any involvement in, is that correct?</p>	<p style="text-align: right;">Page 36</p> <p>1 there was a -- if there was an issue or problem  2 with the manufacturing license ARCOS reporting  3 at Hobart you would sometimes get involved in  4 that. Do you recall any particular issues or  5 problems that arose from time to time?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. Nothing particular. If there was --  8 an error on the report came back and Carrie  9 couldn't figure out what it was, I would help  10 her.</p> <p>11 BY MR. GOTTO:</p> <p>12 Q. In any of the -- you indicated early  13 on that there have been a number of  14 DEA-sponsored seminars or other training  15 sessions that you've attended. Has ARCOS  16 reporting been a subject of any of those  17 sessions?</p> <p>18 A. Yes.</p> <p>19 Q. And what's been the substance of that,  20 that you can recall?</p> <p>21 A. It was DEA training on the transaction  22 codes and the format. That's where they  23 introduced us to the new ARCOS portal for us to  24 be able to upload and what direction they were</p>
<p style="text-align: right;">Page 35</p> <p>1 A. I was aware of it. I would help if  2 there was a problem. But I was not the primary  3 person responsible for reporting.</p> <p>4 Q. Okay. Do you know who was the primary  5 person responsible for reporting?</p> <p>6 A. Prior to 2005 was Sabrina Fountain,  7 After 2005 was Carrie Johnson.</p> <p>8 Q. Okay. And currently the person who  9 does that reporting reports to you, is that  10 correct?</p> <p>11 A. Yes.</p> <p>12 Q. And who is that?</p> <p>13 A. Carrie Johnson.</p> <p>14 Q. So since April of 2017, are you  15 involved in actually working on the preparation  16 of the manufacturing license ARCOS report for  17 the Hobart facility?</p> <p>18 A. No.</p> <p>19 Q. Do you, in your capacity supervising  20 Ms. Johnson, do you review anything -- any of  21 the work that she does relative to that ARCOS  22 reporting?</p> <p>23 A. No.</p> <p>24 Q. You indicated that prior to 2017, if</p>	<p style="text-align: right;">Page 37</p> <p>1 moving in and, you know, what transaction codes  2 to use for what specific business activity.</p> <p>3 Q. Okay. One of the other subject  4 matters you indicated you had responsibility for  5 is losses in transit. What did you mean by that  6 phrase?</p> <p>7 A. So if the carrier -- if there was  8 damage or a loss while the product was in  9 transportation to the customer.</p> <p>10 Q. Okay. And is that something that's  11 the subject of a regular report, or is it  12 something that's just reported on as it occurs?</p> <p>13 A. Reported on as it occurs.</p> <p>14 Q. And how do you -- how would you become  15 aware of the circumstances that would then give  16 rise to such a report?</p> <p>17 A. We're either notified by the carrier  18 that they have a box that was damaged in  19 transit, or a customer may contact our customer  20 service department and say they received a box  21 that was damaged in transit.</p> <p>22 Q. Okay. And so once you receive word of  23 such an event, what do you do to act on that?</p> <p>24 A. If there's just damage only, then we</p>

<p style="text-align: right;">Page 38</p> <p>1 would notify the carrier, give them the tracking                  2 information, make them aware of the damage.                  3 Corporate tracks them on a scorecard. I don't                  4 know the details to that.                  5 And if there was contents missing,                  6 then we would work with the carrier to find out                  7 what happened to those contents and if they can                  8 be recovered.                  9 Q. And is that something you personally                  10 are involved in, working with the carrier when                  11 there's missing contents?                  12 A. Yes.                  13 Q. And so how do you go about determining                  14 whether those contents can be recovered?                  15 A. We will contact our security contacts                  16 with the carrier, initiate an investigation,                  17 they will start looking for the product in their                  18 facilities and everywhere that package                  19 transitioned. And it's typically the box has                  20 busted open while handling on their automated                  21 machinery and a case has become separated, in                  22 which it goes to overgoods, and then overgoods                  23 notifies me that they have Mallinckrodt product.                  24 We bring it back to the distribution center and</p>	<p style="text-align: right;">Page 40</p> <p>1 the DEA?                  2 A. It's their loss/theft report. It                  3 gives the details around the shipment and the                  4 product and quantity that is unaccountable.                  5 Q. And is there such a report prepared                  6 any time any amount of controlled substances is                  7 lost in transit and not otherwise accounted for?                  8 A. I don't understand the question.                  9 Q. Well, so the 106 report, let me ask it                  10 a different way, is that prepared on an                  11 event-by-event basis that there was a particular                  12 loss in transit that where a product cannot be                  13 accounted for ultimately and, therefore, that                  14 gives rise to a particular 106 report that goes                  15 to the DEA?                  16 A. Yes.                  17 Q. And would that be -- is there any                  18 minimum amount of missing product that if you                  19 fall below the minimum you don't have to do the                  20 106 report, anything like that?                  21 A. Mallinckrodt's policy is to report any                  22 controlled substances not accounted for.                  23 Q. Okay. Even if it was one bottle?                  24 A. Yes.</p>
<p style="text-align: right;">Page 39</p> <p>1 send it for destruction.                  2 Q. And overgoods is what?                  3 A. Overgoods is the department in which                  4 our specific carrier -- any loose box that's                  5 found anywhere within their system and they                  6 can't determine where it was coming from or                  7 where it was going to because it's not in its                  8 original shipping container with the labels goes                  9 to overgoods, and then they inventory it, and                  10 we'll have dedicated trace agents to be able to                  11 try to locate who was either the shipper or the                  12 recipient of that product.                  13 Q. Okay. So if the -- do losses in                  14 transit ever result in a report that goes to the                  15 DEA?                  16 A. Yes.                  17 Q. Under what circumstances?                  18 A. If the material is not located in                  19 overgoods we will file a DEA 106 report, notify                  20 them immediately.                  21 Q. Okay. And is that something that                  22 you're responsible for preparing?                  23 A. Yes.                  24 Q. And what does the 106 report report to</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. Or one pill?                  2 A. Yes.                  3 Q. Can you give me a sense for the                  4 frequency, and if this changed over time how it                  5 changed over time, the frequency of filing 106                  6 reports with the DEA that you worked on?                  7 A. There's not a frequency. It's if you                  8 have a loss that can't be accounted for, you                  9 report it.                  10 Q. Sure. I understand.                  11 In a typical, say, month period, do                  12 you have an estimate of how many 106 reports on                  13 average you would have filed?                  14 A. In what time frame?                  15 Q. Well, again, if it changed over                  16 time -- really the entire time that you've been                  17 responsible, but if it's changed over time, you                  18 know, how that's changed.                  19 MR. O'CONNOR: Objection to form.                  20 A. We had more frequent losses in transit                  21 when we were using one particular carrier                  22 service, so I don't remember exactly. I know                  23 that there was more, which is the reason we                  24 changed the carrier service and upgraded to an</p>



<p style="text-align: right;">Page 42</p> <p>1 express service in which our packages got more  2 prioritized handling and pre-alerts so that each  3 station knew when a Mallinckrodt package was  4 coming through so that they could watch it and  5 make sure it was under CCTV coverage, and our  6 106s dropped dramatically. Currently I file  7 maybe, rough estimates, I don't have my records  8 in front of me, four to five a year.  9 BY MR. GOTTO:  10 Q. So the carrier that you changed from,  11 who was the carrier that you had more loss  12 experience with?  13 A. It was FedEx Ground service, which  14 back in that -- in the early time was formerly  15 known as RPS, Roadway Packaging Services. And  16 they weren't handling our product appropriately  17 and we were experiencing a lot of damages, so  18 our corporate transportation team transitioned  19 to FedEx Express services.  20 Q. Okay. Do you recall when that --  21 about when that transition occurred?  22 A. I don't recall exactly.  23 Q. Was it, say, before 2012?  24 A. Yes.</p>	<p style="text-align: right;">Page 44</p> <p>1 106, and then you subsequently find out from  2 FedEx that they're able to locate the product,  3 do you then update the DEA on that, or --  4 A. Yes. We file an amended DEA 106 and  5 send the DEA a cover letter stating that the  6 material has been recovered and brought back to  7 the distribution center and destroyed.  8 Q. Okay. So your estimate, I realize  9 it's a rough estimate, of four to five 106  10 reports a year for the last several years, are  11 those 106 reports as to which ultimately the  12 product was never actually recovered? Is that  13 fair?  14 A. I don't know without looking at the  15 records.  16 Q. Okay. That estimate of roughly four  17 to five a year, would that go back to as far  18 back as whenever it was that you made the  19 transition away from FedEx Ground?  20 A. I'd have to look at the records. I  21 know what currently, they're approximately four  22 to five years -- or four to five a year. I  23 don't recall specifically what they are prior,  24 for past years.</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. Before 2010?  2 A. It was mid 2000s. Could have been '5,  3 '6, '7, '8.  4 Q. So probably before 2010?  5 A. Yes.  6 Q. Okay. And were the problems primarily  7 damage, or were they losses that ultimately  8 couldn't be accounted for?  9 MR. O'CONNOR: Object to form.  10 A. They were predominantly damages.  11 BY MR. GOTTO:  12 Q. Okay. And so am I understanding  13 correctly if there's damage but the product is  14 all accounted for, that doesn't result in a 106  15 report, correct?  16 A. It depends on whether it was recovered  17 quickly, because we have to report within  18 24 hours. So if we could report -- if we could  19 recover within FedEx within 24 hours and we knew  20 they had the product, it was in as overgoods,  21 then we would not file. If we couldn't locate  22 the product within 24 hours, we would file.  23 Q. Okay. And what would happen if you  24 couldn't locate within 24 hours so you filed the</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. Okay. So, for example, let's say that  2 2010 to 2014 time frame, do you have any sense  3 of how -- of the average number of 106 reports  4 that were filed in that time frame?  5 A. No, I don't.  6 Q. Okay. During the period of when you  7 were using FedEx Ground, do you have a sense for  8 approximately how many, on average, how many  9 106s on average were filed annually?  10 A. Not an exact number. It was  11 significantly higher than what we currently  12 have.  13 Q. Was it twice as many?  14 A. I don't remember exactly.  15 Q. Okay. I'd like to understand, and I  16 realize since 2001 we're dealing with a long  17 time period here and some of this is going to  18 necessarily be, you know, a little fuzzy perhaps  19 as to specific dates and that sort of thing, but  20 I'd like to understand how your job  21 responsibilities changed over the years, if they  22 have changed. So if you can just -- let's start  23 with sort of a general description of how those  24 responsibilities have changed over the years.</p>

<p style="text-align: right;">Page 46</p> <p>1 A. So I have received promotions  2 throughout the years into different levels  3 within the compliance group. I started out with  4 just basic clerical, the ARCOS reporting, data  5 entry of waste transactions, discrepancy  6 reporting with the carriers. Then my  7 responsibilities increased in which I took on  8 facilitating and organizing the destruction of  9 the waste, not just doing the data entry. Took  10 on more responsibility in terms of just  11 workload, still doing the clerical but then  12 doing -- more involved with walk-throughs  13 through the facility, learning more about CFR  14 and the regulations, attended the training  15 seminars, learned about quota, and then I was a  16 compliance analyst for a length of time, and  17 then promoted into senior controlled substance  18 compliance coordinator, facilitated DEA audits,  19 was the DEA contact, was on the CSOS working  20 team when DEA was instituting CSOS to our  21 electronic 222 forms, and then was promoted into  22 the role of manager in April of 2017.  23 Q. Great. Thank you. Let's go through  24 some of those items.</p>	<p style="text-align: right;">Page 48</p> <p>1 substance, and those get -- they're documented,  2 weighed, documented on our destruction reports.  3 We enter -- our team enters that into our  4 computer system, which then currently sends all  5 of the waste to a waste distributor for  6 destruction by incineration.  7 Q. And you indicated your team still  8 does -- is still responsible for that. Who on  9 your team currently has that responsibility?  10 A. Carrie Johnson has the data entry  11 portion.  12 Q. Okay. Next item you indicated was  13 discrepancy reporting. What's that?  14 A. So that's what we were talking about  15 earlier with the carriers -- excuse me, with the  16 carriers that if there's any discrepancies in  17 what we ship versus what the customer ordered,  18 or if the customer ordered a wrong product or we  19 shipped a wrong product in error, any difference  20 than what was intended to be ordered.  21 Q. Okay. And so some of those  22 discrepancies are the result of damage in  23 transit, the sort of thing you discussed --  24 described a little earlier today. It sounds</p>
<p style="text-align: right;">Page 47</p> <p>1 I think we've -- the ARCOS reporting  2 responsibility, I think you've already  3 described, is a continuing one that you still  4 have for the distribution license at Hobart,  5 correct?  6 A. Yes.  7 Q. Apart from the testimony you've  8 already given us this morning, is there any  9 other aspect of ARCOS reporting that's been your  10 responsibility?  11 A. Currently?  12 Q. Or at any time.  13 A. Well, currently the manufacturing is  14 done by a person who reports to me, so I oversee  15 that. But nothing else in regards to ARCOS.  16 Q. Okay. And waste data entry, which  17 you'd indicated was an early on responsibility,  18 is that something you still have responsibility  19 for?  20 A. My team, but not myself.  21 Q. And what does that waste data entry  22 consist of?  23 A. So we track every single tablet,  24 powder, capsule of waste that's a controlled</p>	<p style="text-align: right;">Page 49</p> <p>1 like sometimes there's a misfilling of an order,  2 though. What happens in those situations?  3 MR. O'CONNOR: Objection to form.  4 A. Because of our cycle count program in  5 the processes in the distribution center, we  6 have not had in the last ten years a shipping  7 error where we meant to ship sugar-free and we  8 shipped cherry or something, because of the bar  9 coding system.  10 Prior to that there could have been an  11 instance where the wrong product was shipped,  12 and then the customer would say, hey, we've  13 received the wrong product, we'd make  14 arrangements to issue them a 222 form, we would  15 document what happened, that it was our mistake,  16 how we fix it, and then would make sure that the  17 customer had all of the documentation they  18 needed to document what happened, that they  19 received the wrong item, it was returned back to  20 Mallinckrodt, we received the incorrect item, we  21 sent it for destruction.  22 BY MR. GOTTO:  23 Q. Okay. And you also indicated  24 sometimes the customer may have ordered the</p>



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1 wrong item.  
 2 A. Frequently we have situations where a  
 3 customer will enter the wrong item in their  
 4 order entry screen. They want buprenorphine  
 5 8.2-milligram and they ordered buprenorphine  
 6 2.5-milligram and they get it and it's the wrong  
 7 product and they have to send it back to us.  
 8 And that's frequent we have customer ordering  
 9 errors.  
 10 Q. Okay. And in that situation, is there  
 11 any sort of report that gets generated when that  
 12 happens, or --  
 13 A. The --  
 14 Q. -- how is it handled?  
 15 A. I apologize.  
 16 The discrepancy report would document  
 17 what transpired, and then we would document  
 18 appropriately what actions we took to rectify.  
 19 Q. Okay. And that discrepancy reporting,  
 20 is that something that you're personally  
 21 involved in?  
 22 A. Yes.  
 23 Q. Another item you mentioned was  
 24 destruction of waste. Is that the process you

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1 have described a few moments ago where you  
 2 shipped the waste to a reverse distributor for  
 3 destruction?  
 4 A. Yes.  
 5 Q. And is that -- shipment of that waste,  
 6 is that documented with the DEA somehow?  
 7 A. It's -- if they're C1 and 2s, they are  
 8 documented by a 222 form; 3, 4s and 5s, a  
 9 transfer of controlled substance form, and it is  
 10 ARCOS reported as well.  
 11 Q. Okay. So the -- either the 222 form  
 12 or the transfer form that you mentioned, are  
 13 those things that you have responsibility for?  
 14 A. Yes.  
 15 Q. Is there a regular process for the  
 16 destruction of waste, or is it handled on an  
 17 as-needed basis?  
 18 A. Monthly we schedule a pickup by the  
 19 reverse distributor to take care of all of the  
 20 waste generated from the previous month because  
 21 it has to be stored in cages and vaults, so if  
 22 we don't have it removed monthly, we tend to run  
 23 into space problems.  
 24 Q. Okay. Another thing you mentioned

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1 were walk-throughs. What did you mean by that?  
 2 A. So we go up on the manufacturing floor  
 3 and just walk through the facility daily to make  
 4 sure that materials are being stored in  
 5 compliance with the regulations, there's nothing  
 6 being left out, there's no residual powders  
 7 anywhere they shouldn't be, everything is  
 8 sealed. Just being there for questions for the  
 9 floor, if somebody has a question, how do they  
 10 handle something.  
 11 Q. Okay. And so when you say we do that  
 12 daily, who is "we" in that setting?  
 13 A. I do it daily. When I'm not there, a  
 14 member of my team will do it.  
 15 Q. So describe for me, if you would, the  
 16 Hobart facility, just the physical setup  
 17 relative to your office. For example, since you  
 18 walk through it daily, about how large is the  
 19 facility?  
 20 A. I'm not -- I don't know square footage  
 21 or any of that kind of thing. It's a big  
 22 facility, but I don't know the square footage.  
 23 Q. Is it multi-story?  
 24 A. Yes, there are multiple floors.

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1 Q. Okay. So the walk-through that you do  
 2 every day, how long does it take you?  
 3 A. 45 minutes to an hour.  
 4 Q. Okay. Are there particular things you  
 5 look for when you're doing the walk-through?  
 6 A. Just to make sure everything is stored  
 7 appropriately and within compliance.  
 8 Q. And one of the -- actually right after  
 9 the walk-throughs you indicated learning more  
 10 about the CFRs and regulations, and part of your  
 11 walk-through, I take it, is to satisfy yourself  
 12 that the facility is in compliance with  
 13 applicable regulations, correct?  
 14 A. To ensure we're always in compliance,  
 15 yes.  
 16 Q. And so describe for me the process  
 17 you've gone through over the years to learn  
 18 about and stay current on the applicable  
 19 regulations.  
 20 A. So I've read CFR a number of times. I  
 21 refer to it often if there's questions. If we  
 22 were unsure of an interpretation of CFR, we may  
 23 have reached out for DEA to their field office  
 24 for interpretation or asked them while they were

<p style="text-align: right;">Page 54</p> <p>1 on-site for an audit, so I've learned from DEA  2 what their expectations are, what they want. I  3 attended the DEA training seminars that are  4 sponsored by DEA in which they go over their  5 expectations or break down CFR into more detail.  6 We do practice exercises on quota at  7 those training seminars, they talk about imports  8 and exports, how to fill out the forms, and how  9 to do the calculations in the way that they want  10 them so that they can process them more  11 efficiently.  12 Q. Okay. Is that a -- do you still go to  13 the seminars that DEA sponsors?  14 A. When they have them. They haven't  15 been having them as more -- as frequently as  16 they did. They used to have them every other  17 year, and it's been a couple of years since  18 they've had them.  19 Q. Okay. So during the time since 2001  20 when you became involved in compliance, about  21 how many DEA-sponsored trainings have you been  22 to?  23 A. More than a dozen.  24 Q. And are these multi-day programs?</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. Which are those?  2 A. Suspicious order monitoring, state  3 licensing, exports. DEA has an initiative with  4 streamlining the Customs documentation through a  5 database with exports.  6 Q. So let me be sure -- I just want to be  7 sure I've covered all the various sort of formal  8 DEA-related training conferences and seminars  9 that you've gone to.  10 You indicated about a dozen or so of  11 the DEA-sponsored programs, although there  12 hasn't been one in the last at least couple of  13 years, correct?  14 A. Correct.  15 Q. And the Buzzeo, those are one a year?  16 A. Annual, yeah.  17 Q. Okay. Are there other training  18 programs of that type that you've attended?  19 A. NADDI, but not -- NADDI, they have DEA  20 speakers sometimes, but it's more about what's  21 going on in the industry.  22 Q. And do you attend the NADDI  23 conferences regularly?  24 A. I have occasionally.</p>
<p style="text-align: right;">Page 55</p> <p>1 A. Usually they're two days.  2 Q. And you also indicated you attended  3 the Buzzeo training, correct?  4 A. Yes.  5 Q. How often have you done that?  6 A. Just about every year.  7 Q. Up to the current?  8 A. Yes.  9 Q. What's the subject matter that's  10 typically covered at the Buzzeo conferences?  11 A. They usually have a DEA speaker that's  12 talking about NPRMs and what's on their agenda  13 and what they're working on. They'll have  14 subject matter experts on state licensing, and  15 different laws that individual states are  16 enacting in regards to controlled substances.  17 They'll have roundtable discussions on industry  18 topics. It's usually a two-and-a-half-day  19 conference.  20 Q. Okay. Are there particular, for  21 example the roundtable discussions, particular  22 ones that you make a point of participating in  23 at these conferences?  24 A. Yes.</p>	<p style="text-align: right;">Page 57</p> <p>1 Q. About how many times?  2 A. Half dozen roughly.  3 Q. How recently can you recall going to  4 one?  5 A. Last year. I went to a NADDI  6 conference last year.  7 Q. Are they annual?  8 A. They are.  9 Q. Okay. Apart from NADDI, Buzzeo, and  10 the DEA-sponsored, any other ones you can think  11 of?  12 A. Years ago I attended the  13 Pharmaceutical Security Coalition, PSC, many  14 years ago, and it was only once. It was more  15 geared towards physical security.  16 Q. In one of your answers a moment ago  17 you made reference to NPRM?  18 A. Notice of proposed rulemaking.  19 Q. Okay. Thank you.  20 Do you recall any particular proposed  21 rules that were covered in any of the  22 conferences you attended?  23 A. Recently there is one for paper.  24 They're trying to eliminate the carbon 222</p>

<p style="text-align: right;">Page 58</p> <p>1 forms, so there's been a Notice of Proposed          2 Rulemaking for one-page 222 forms. And there          3 was a recent one, but off the top of my head          4 it's escaping me.          5 Q. Okay.          6 A. Quota, there's a recent NPRM regarding          7 quota.          8 Q. You've mentioned quota a couple of          9 times. What's been your responsibility over the          10 years with respect to quota?          11 A. Initially I had very little to do with          12 quota. In more recent years I've been involved          13 with compiling and reviewing the quota letters          14 for increases throughout the year. The initial          15 quota requests are prepared by my team, and I          16 review.          17 Q. When you say "quota," what do you --          18 just so the record is clear what we're talking          19 about here, what do you mean by quota?          20 A. Quota is the DEA allocation system          21 to -- for the manufacturing of controlled          22 substances.          23 Q. And would your involvement be with          24 respect to the manufacturing activities at the</p>	<p style="text-align: right;">Page 60</p> <p>1 I would assist and review for a second set of          2 eyes, and then Karen Harper ultimately approved          3 the letter for submission. Carrie at that time          4 prior to 2017 reported directly to Karen Harper.          5 Q. Okay. And so the actual submission,          6 has that always been Ms. Harper's          7 responsibility?          8 A. To review -- I need clarification of          9 actual submission, entering into the database          10 or --          11 Q. Yeah. Well, let me back up.          12 You said -- you made reference to your          13 involvement being a second set of eyes. Was          14 there any time when you had more involvement          15 than simply being a second set of eyes?          16 A. Currently I do.          17 Q. Okay. And so when did you take on          18 that additional responsibility?          19 A. When Carrie Johnson started reporting          20 to me.          21 Q. In 2017?          22 A. Yes.          23 Q. Okay. So prior to 2017 when          24 Ms. Johnson started to report to you, in the</p>
<p style="text-align: right;">Page 59</p> <p>1 Hobart facility?          2 A. Yes, quota only applies to the          3 manufacturing license. It doesn't apply to the          4 distributor license.          5 Q. And is it specific to facility by          6 facility?          7 A. Yes.          8 Q. Okay. And so to the extent there's a          9 quota for Mallinckrodt St. Louis facility,          10 that's not something you have involvement with,          11 is that correct?          12 A. Correct.          13 Q. Okay. Do you know who has the          14 corresponding role, the role that corresponds to          15 your role at Hobart with respect to the          16 St. Louis quota for manufacturing?          17 A. That would be my counterpart, Dave          18 Hunter.          19 Q. Okay. And the quota that -- focusing          20 on the Hobart-related quota that you do have          21 responsibility for, when did you first have          22 responsibility for quota?          23 A. So it was predominantly overseen by          24 Karen Harper, it was compiled by Carrie Johnson,</p>	<p style="text-align: right;">Page 61</p> <p>1 second set of eyes role that you mentioned, what          2 did your activities consist of with respect to          3 quota?          4 A. Remote -- reviewing it for grammatical          5 content in terms of if I had heard through my          6 role maybe we had taken on a new contract or          7 been awarded business and Carrie hadn't included          8 that in a request, I would remind her about that          9 or let her know about that so it could be          10 inclusive in the request advising DEA of all the          11 information that we had available to us.          12 Q. Okay. And you indicated that          13 initially you had very little responsibility          14 for -- with quota, and that changed over time.          15 Did you have more responsibility when you began          16 reporting to Ms. Harper?          17 MR. O'CONNOR: Objection to form.          18 A. I don't understand the question.          19 BY MR. GOTTO:          20 Q. I'm just trying to understand when you          21 started to have this additional responsibility,          22 the second eyes review of the quota          23 applications.          24 A. So that would have been -- I got more</p>

<p style="text-align: right;">Page 62</p> <p>1 involved in roughly '14, '15, 2014, 2015.</p> <p>2 Carrie and I both reported to Karen. Carrie had</p> <p>3 her set of responsibilities. I had my set of</p> <p>4 responsibilities. But in roughly '14 or '15, I</p> <p>5 was cross-training more and taking on more</p> <p>6 responsibilities to advance to manager, so in</p> <p>7 that learning I needed to learn more about</p> <p>8 quota, so then I started getting more involved</p> <p>9 in quota.</p> <p>10 Q. Okay. So what did you do to learn</p> <p>11 more about quota?</p> <p>12 A. More thorough on the letters,</p> <p>13 understanding them, learned more about the</p> <p>14 market and the dynamics that go on in the supply</p> <p>15 chain, and the quota section training on the --</p> <p>16 from the DEA seminars.</p> <p>17 Q. And so the DEA seminars on quota</p> <p>18 training, what are the topics they cover in that</p> <p>19 context?</p> <p>20 A. Research versus manufacturing, where</p> <p>21 does the quota belong, when do you start needing</p> <p>22 quota. Karen mentored me because she had a lot</p> <p>23 of experience with quota.</p> <p>24 Q. So when you say "research versus</p>	<p style="text-align: right;">Page 64</p> <p>1 then if that initial grant is not enough to</p> <p>2 support, get you through the full calendar year,</p> <p>3 you can ask for more quota throughout the year.</p> <p>4 Q. Okay. And so that initial grant is</p> <p>5 granted with respect to an upcoming calendar</p> <p>6 year?</p> <p>7 A. Yes, it's applied for on April 12th of</p> <p>8 the preceding year, so we take -- for example,</p> <p>9 this April 1st coming up we will take our supply</p> <p>10 plan for 2020 of what's needed in the market and</p> <p>11 convert that into API, so how much API we need,</p> <p>12 and then that will be applied for with DEA by</p> <p>13 April 1st for 2020.</p> <p>14 Q. Okay. And then the DEA acts on that</p> <p>15 application at some point prior to the upcoming</p> <p>16 January 1, provides the quota allocation for the</p> <p>17 upcoming calendar year, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And so the quota allocation -- when</p> <p>20 you say API, I mean, that's active</p> <p>21 pharmaceutical ingredient, correct?</p> <p>22 A. Yes.</p> <p>23 Q. And so is the quota for -- that the</p> <p>24 DEA grants for the upcoming year, is that on an</p>
<p style="text-align: right;">Page 63</p> <p>1 manufacturing," what did you mean by that?</p> <p>2 A. So there's researcher license and</p> <p>3 there's manufacturing licenses, and quota is not</p> <p>4 required on a research license but it is</p> <p>5 required on a manufacturing license, so what</p> <p>6 project development work can be executed under a</p> <p>7 research license not requiring quota, and what</p> <p>8 project development work needs to be executed on</p> <p>9 a manufacturing license that does require quota.</p> <p>10 Q. Okay. And is that also what you meant</p> <p>11 when you said when you start needing quota, is</p> <p>12 that this research versus manufacturing</p> <p>13 distinction?</p> <p>14 A. No, when we start needing quota is</p> <p>15 when the current quota is not sufficient for our</p> <p>16 demand plan and we need to ask for more quota,</p> <p>17 reviewing the market demand, the -- what's</p> <p>18 needed, and how much we have will last us.</p> <p>19 Q. Describe for me generally how the</p> <p>20 quota process works from your perspective. The</p> <p>21 DEA provides a quota allocation for the Hobart</p> <p>22 manufacturing facility from time to time,</p> <p>23 correct?</p> <p>24 A. Yes. We have an initial grant, and</p>	<p style="text-align: right;">Page 65</p> <p>1 API by API basis?</p> <p>2 A. Yes.</p> <p>3 Q. And is it --</p> <p>4 A. By molecule.</p> <p>5 Q. By molecule.</p> <p>6 Okay. So it isn't with respect to a</p> <p>7 particular dosage, for example, is that right?</p> <p>8 A. I don't understand what you mean.</p> <p>9 Q. So, for example, would you have a</p> <p>10 certain allocation of oxycodone for the calendar</p> <p>11 year as compared to an allocation of</p> <p>12 20-milligram tablets, 30-milligram tablets,</p> <p>13 etcetera?</p> <p>14 A. Yes, your application is submitted by</p> <p>15 dosage form.</p> <p>16 Q. Okay. So for each API, the API is</p> <p>17 then broken down to -- in different dosages?</p> <p>18 A. Yes.</p> <p>19 Q. And that's how, ultimately the DEA</p> <p>20 when they grant the quota, that's how it's</p> <p>21 granted?</p> <p>22 A. I don't know what formula DEA uses to</p> <p>23 grant it. We fill our application, and we tell</p> <p>24 DEA what we want and what we're going to make</p>

<p style="text-align: right;">Page 66</p> <p>1 with it. Very, very seldom do we get a  2 100 percent grant.  3 Q. Okay. But whatever grant you get, it  4 is expressed in terms of by API by dosage?  5 A. When we are given the grant we are  6 given just the total API, so we apply for it  7 specifying the dosage, but when the grant comes  8 there's no dosage specified, and if they haven't  9 given us 100 percent we don't know what they're  10 expecting us to make with it.  11 Q. Okay. So let's just use oxycodone for  12 an example, that's an API, correct, oxycodone?  13 A. Yes.  14 Q. Okay. And so when you submit the  15 application, you would have that broken down in  16 various dosages?  17 A. Yes.  18 Q. And a certain number of tablets in  19 each dosage, correct?  20 A. Yes.  21 Q. And you could add up how many  22 molecules are in all those tablets and then come  23 up with a gross amount of oxycodone API that's  24 covered by your application, correct?</p>	<p style="text-align: right;">Page 68</p> <p>1 the quota that was granted?  2 A. No.  3 MR. GOTTO: Okay. Why don't we take a  4 short break. We've been going for over an hour.  5 THE VIDEOGRAPHER: The time is  6 10:13 a.m., and we're off the record.  7 (Whereupon, a recess was taken.)  8 THE VIDEOGRAPHER: The time is  9 10:31 a.m., and we're on the record.  10 BY MR. GOTTO:  11 Q. Ms. Spaulding, before we broke we  12 were -- you were testifying about the quota  13 process and some aspects of it. And if I  14 understand correctly, from time to time there  15 can be applications for an update to the quota  16 during the calendar year, is that correct?  17 A. An increase, yes, we can request an  18 increase at any time.  19 Q. And is that a process that you're  20 involved in?  21 A. What time frame?  22 Q. Well, have you been involved in it at  23 any time frame since you've been at  24 Mallinckrodt?</p>
<p style="text-align: right;">Page 67</p> <p>1 A. That's what the application amount was  2 for, what all those dosage units compile total.  3 Q. Okay. But then when the DEA actually  4 grants the quota, it's simply an amount of that  5 API?  6 A. Yes.  7 Q. Okay. And so -- and that grant, as  8 you indicated, may -- or frequently is less than  9 the gross amount that was applied for, correct?  10 A. Correct.  11 Q. And so when that happens, do you have  12 an understanding once you have that quota grant  13 and, let's say, it's less than the gross amount  14 that was applied for, what that -- what the  15 Hobart facility is permitted to then manufacture  16 in terms of different dosages under that quota  17 grant?  18 A. So the business will decide based on  19 the demand plan and the market demand what we'll  20 make with the quota that we've been granted.  21 Q. Okay. And so is there any need to go  22 back to the DEA for any further update on the  23 quota or clarification once you make the  24 determination of what to manufacture in light of</p>	<p style="text-align: right;">Page 69</p> <p>1 A. Yes.  2 Q. Okay. And what's been your  3 involvement in that process?  4 A. As we discussed earlier, began as a  5 second set of eyes, then took on additional  6 responsibilities, and now currently I oversee  7 the person who compiles them, and I review them  8 before submission.  9 Q. Okay. In your experience, is it --  10 what's the frequency with which there are --  11 Mallinckrodt with respect to the Hobart facility  12 has made application for increase in quota?  13 A. Depends on the molecule. Some  14 molecules we get enough for our demand, and some  15 molecules we have to ask. Depends on the market  16 and disruptions. If another manufacturer is out  17 of supply, the distributors could be attempting  18 to get for us, so we're going to consume our  19 quota faster than anticipated. There's many  20 different factors.  21 Q. Okay. Is it -- has it ever been your  22 experience since you've been at Mallinckrodt  23 that with respect to -- well, strike that.  24 When you have worked on an application</p>



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1 for a quota increase, what are the steps that go  
2 into that process?  
3 A. We first take a look at what we've  
4 sold versus what we need to make for the rest of  
5 the year. We subtract out what we've been  
6 granted, and DEA has a formula that involves  
7 what you have on your end inventory, what you  
8 were granted, minus what you've sold in your  
9 forecast, and we will run those formulas to see  
10 if we have justification to have an increase for  
11 that calendar year. If a justification, meaning  
12 this formula, shows that we have a shortfall and  
13 that based on our sales we are entitled to more  
14 quota, then we will submit a request.  
15 Q. Okay. And I think you testified  
16 before the break that it is sometimes the case  
17 that the quota that's granted for a calendar  
18 year is less than what was applied for, correct?  
19 A. Yes, and many times it's less.  
20 Q. Okay. And so if the quota -- let's  
21 say the quota was granted for less than what was  
22 applied for, and sales of that particular API  
23 are consistent with what the forecast had been,  
24 so as the year is unfolding, consistent with

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1 what your application originally showed, you'd  
2 be running short, correct, if the quota was less  
3 than what you applied for, correct?  
4 A. Correct.  
5 Q. And so in that situation, would you  
6 apply for increased quota?  
7 A. Yes.  
8 Q. Okay. So it could sometimes be the  
9 case that the application for increased quota  
10 could show sales consistent with what had  
11 previously been forecast, but the shortage  
12 arising from the fact that the quota that was  
13 granted was less than had been applied for?  
14 A. Yes.  
15 MR. O'CONNOR: Object to form.  
16 BY MR. GOTTO:  
17 Q. And then sometimes it may be the case  
18 that sales were actually greater than what had  
19 been forecast for one reason or another, and a  
20 shortage from the quota results, correct?  
21 A. Yes.  
22 Q. Okay. In your experience, what's the  
23 time frame approximately for the DEA to act on a  
24 request for increased quota?

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1 A. Currently?  
2 Q. Sure, start with currently.  
3 A. It's in the neighborhood of six to  
4 eight weeks.  
5 Q. Okay. Has that changed over the  
6 years?  
7 A. Yes. Several years ago it was in  
8 excess of 12 to 16 weeks, which is very  
9 difficult on the manufacturers because of lead  
10 times when we have to wait so long to get a  
11 quota grant, or to even know if we're going to  
12 get quota, to be able to plan our pipeline and  
13 our manufacturing, so when there was greater  
14 review within DEA and it could take four to six  
15 -- 14 to 16 weeks. Currently we're experiencing  
16 about six to eight weeks.  
17 Q. And approximately what was the time  
18 frame when the longer time period applied?  
19 A. I don't remember the years, but it was  
20 when Joe Rannazzisi was head of DEA and was  
21 reviewing and signing all quota requests.  
22 Q. Okay. So it was your understanding  
23 there was a period of time when the actual head  
24 of the DEA personally reviewed and signed off on

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1 each quota request?  
2 A. Yes.  
3 Q. And do you know currently what the --  
4 who at the DEA reviews and signs off on quota  
5 requests?  
6 A. No, I don't.  
7 MR. GOTTO: Can we go off the record  
8 one second?  
9 THE VIDEOGRAPHER: The time is  
10 10:37 a.m., and we're off the record.  
11 (Pause.)  
12 THE VIDEOGRAPHER: The time is  
13 10:38 a.m., and we're on the record.  
14 BY MR. GOTTO:  
15 Q. So, Ms. Spaulding, when -- currently  
16 when there's a request for a quota increase, is  
17 that typically made as to one specific API?  
18 A. Each quota request is by molecule.  
19 Q. Okay. And is there, in your  
20 experience, is there a process of any sort of  
21 interaction with the DEA when the quota request  
22 is made? Is there back and forth with the DEA,  
23 or do you simply wait for them to act on it and  
24 see what they do?



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1 MR. O'CONNOR: Object to form.  
 2 A. Sometimes, sometimes, most commonly we  
 3 just have to wait until we receive a letter.  
 4 But if DEA wants additional information, like  
 5 who we're selling to or detailed sales  
 6 information, they'll e-mail us and ask for  
 7 whatever additional information they want for  
 8 use in reviewing our request.  
 9 BY MR. GOTTO:  
 10 Q. Okay. And is it your experience that  
 11 generally do they ask for more information, or  
 12 is that kind of an exceptional circumstance when  
 13 they do that?  
 14 A. It's an exception to the rule.  
 15 Q. With respect to the Hobart  
 16 manufacturing quota, who is it at Mallinckrodt  
 17 that's had primary responsibility for submitting  
 18 the applications and any applications for  
 19 increased quota?  
 20 A. Primary responsibility is Carrie  
 21 Johnson. She makes the application in the  
 22 database, and drafts the letters of which myself  
 23 and Karen review prior to submitting.  
 24 Q. Okay. And who is it at Mallinckrodt

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1 that has the authority to determine the amount  
 2 of quota that will be requested from time to  
 3 time?  
 4 A. I'm not sure I understand. Who is  
 5 signing the letters?  
 6 Q. Well, that would be -- one question  
 7 would be who signs the letters, sure.  
 8 A. Carrie Johnson is the applicator,  
 9 because we have log-ins with DEA, so as she's  
 10 the person filling in the data using her log-in  
 11 to DEA's database, she is the person that signs  
 12 the letters.  
 13 Q. Okay. Does she have the authority to  
 14 make the decision as to the amount of quota that  
 15 will be requested of the DEA either in an annual  
 16 request or request for increase?  
 17 A. No, they're all reviewed, and either  
 18 Karen or myself would approve them.  
 19 Q. Okay. Do you have an authority to  
 20 approved without Ms. Harper's authorization?  
 21 A. For routine requests such as the  
 22 initial, which there's no extraordinary  
 23 circumstances, yes. If there's anything  
 24 unusual, extraordinary, any outlying factors,

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1 then Karen would be -- would review and approve.  
 2 Q. Okay. So the initial, when you say  
 3 "the initial," you mean the calendar year  
 4 requests that you described was due April 1st of  
 5 each year?  
 6 A. Yes.  
 7 Q. And so what's the process that you go  
 8 through to compile that annual request?  
 9 A. So my team will generate all of the  
 10 forecast data for the next year, because that's  
 11 all we have at that time for a future year's  
 12 forecast, and number of bottles to be sold, and  
 13 then convert that back to amount of API, and  
 14 account for processing waste, samples, and then  
 15 determine a number to meet the demand plan.  
 16 Q. Okay. And when you say your team, who  
 17 is participating in that process?  
 18 A. Carrie is the primary person.  
 19 Q. And the time period during which  
 20 you've had that responsibility for the annual  
 21 quota request, what's that time period?  
 22 A. When Carrie started reporting to me in  
 23 April of 2017.  
 24 Q. Okay. Prior to that time, who was

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1 performing the corresponding duties with respect  
 2 to the annual requests?  
 3 A. Karen.  
 4 Q. And did you assist in that other than  
 5 the second pair of eyes role that you described?  
 6 A. I was copied on e-mails and was  
 7 informed, but I didn't approve.  
 8 Q. Okay. The sales -- I'm sorry. The  
 9 forecast data that supports the quota request,  
 10 how is that compiled?  
 11 A. It's provided to us by our corporate  
 12 planning team.  
 13 Q. Okay. And I think you've already  
 14 testified that it's often the case that the  
 15 quota that's actually granted by the DEA is less  
 16 than what's applied for, is that fair?  
 17 A. Yes.  
 18 Q. So would there -- would it be possible  
 19 to factor that in when you make the application,  
 20 right, apply for more than you think you might  
 21 need on the expectation that the DEA is going to  
 22 grant less than you asked for?  
 23 MR. O'CONNOR: Objection to form.  
 24 A. It's an estimate. It's not hard

<p style="text-align: right;">Page 78</p> <p>1 numbers of what we're going to produce because          2 it's a projection.          3 BY MR. GOTTO:          4 Q. So is there any negative consequence          5 of if you were to apply for -- if you were to          6 receive quota that exceeded what you ultimately          7 turn out to need during that year, is there any          8 negative consequences to that?          9 MR. O'CONNOR: Objection to form.          10 A. I don't think I understand what you're          11 asking.          12 BY MR. GOTTO:          13 Q. Okay. Well, you make your quota          14 application for the year, and if you receive          15 quota that's less than what you actually need,          16 obviously there's a potential negative          17 consequence there that you can't fill the orders          18 that you get?          19 A. Right.          20 Q. And you have to update that and try to          21 get an increase during the year, right? That's          22 one scenario. Sounds like that's not an          23 uncommon scenario, right?          24 A. It's not. If we have excess quota at</p>	<p style="text-align: right;">Page 80</p> <p>1 say frequently. Depends on the molecule.          2 BY MR. GOTTO:          3 Q. And apart from this year-end          4 straddling you described where they allow you to          5 have a certain amount to keep your production          6 straddling the year-end, is there any carryover          7 from year to year of unused quota from one year          8 to the next?          9 A. No, absolutely not. It has to be          10 consumed by 12/31. The API has to be at your          11 facility. If it's not at your facility on          12 12/31, it's use it or lose it.          13 Q. Going back to your -- earlier today          14 you gave me a description of how your          15 responsibilities evolved over the years, and          16 we've been talking about the quota component of          17 that. You indicated that at some point you          18 became a compliance analyst, correct?          19 A. Yes, but it was a title. It wasn't --          20 I wasn't really an analyst. That was under the          21 Tyco days, and they only had certain job          22 descriptions, so I was the only one in the          23 company who did what I did. They didn't really          24 have a job title for controlled substances</p>
<p style="text-align: right;">Page 79</p> <p>1 the end of the year, we review as part of our          2 annual process in September and October if we          3 are going to have excess quota, and we'll          4 relinquish to DEA and let them know that the          5 market has changed, or we had a project we          6 didn't need the quota for, or any number of          7 things that we're going to have excess quota.          8 Now, quota factors in a year-end          9 inventory because of timelines. If you don't          10 get your next calendar year quota on January 1,          11 you're going to be out of supply for two months          12 if you have a product that takes eight weeks to          13 make, so they allow you to have a year-ending          14 inventory so that you have API to start          15 producing to allow for continuous supply. So          16 we'll find out how much we need for a          17 year-ending inventory and what we need to meet          18 our plan, and if we have excess we'll relinquish          19 it to DEA.          20 Q. And does that happen frequently that          21 you have excess quota as you're approaching the          22 year end?          23 MR. O'CONNOR: Objection to form.          24 A. It happens occasionally. I wouldn't</p>	<p style="text-align: right;">Page 81</p> <p>1 compliance associate or coordinator, so I was          2 assigned a job title of analyst because that's          3 where I fit within their career band.          4 Q. Okay. So that was pre-'07, then, if          5 that was during the Tyco time?          6 A. Yeah, roughly. I don't remember          7 exactly, but...          8 Q. And then after Mallinckrodt spun off          9 from Tyco, what -- did you keep the compliance          10 analyst title at that point?          11 A. Under Covidien I believe I was.          12 Q. And I've seen some documents where I          13 think you signed as a compliance investigator.          14 Did you have that title at some point?          15 A. That was the initial role in 2001. I          16 was hired as a compliance investigator. Again,          17 it was a title. I would investigate losses in          18 transit, but I had many responsibilities.          19 Q. Okay. And then you indicated at some          20 point you became the senior controlled substance          21 compliance coordinator?          22 A. Yes.          23 Q. When was that?          24 A. I don't remember exactly when.</p>

<p style="text-align: right;">Page 82</p> <p>1 Q. Do you have an approximate?</p> <p>2 A. Before I was manager.</p> <p>3 Q. Okay.</p> <p>4 A. Sorry, I don't.</p> <p>5 Q. And when did you become manager?</p> <p>6 A. That, I remember, was April of 2017.</p> <p>7 Q. Okay. But in terms of title, it was</p> <p>8 compliance analyst and then compliance</p> <p>9 coordinator and then ultimately manager, is that</p> <p>10 fair?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Now, you indicated one of the</p> <p>13 things you had responsibility for are DEA</p> <p>14 audits?</p> <p>15 A. Yes.</p> <p>16 Q. Tell me what the DEA audit process is</p> <p>17 that you had responsibility with respect to.</p> <p>18 A. So when DEA came on-site to conduct an</p> <p>19 inspection, there's point of contacts that</p> <p>20 interact with the DEA, so there was -- it was</p> <p>21 typically myself and the security manager at the</p> <p>22 time were the two main points of contact with</p> <p>23 the DEA that facilitated the audit, so we would</p> <p>24 be in the front room with the DEA as they were</p>	<p style="text-align: right;">Page 84</p> <p>1 so I was the person pulling the records.</p> <p>2 Elizabeth McPhail would have been the front room</p> <p>3 person. And then after I started reporting to</p> <p>4 the materials manager, I became the front room</p> <p>5 person because Elizabeth McPhail was pulled out</p> <p>6 of the DEA role and I became the lead.</p> <p>7 Q. Was there a reason for that change?</p> <p>8 A. Not that I can remember specifically.</p> <p>9 Q. Do you remember approximate time frame</p> <p>10 when that occurred?</p> <p>11 A. Not exactly, no.</p> <p>12 Q. So in terms of responding to questions</p> <p>13 that the DEA would pose during these audits,</p> <p>14 what sorts of questions can you recall the DEA</p> <p>15 posing to you?</p> <p>16 A. Pretty standard audit questions, who</p> <p>17 do you use for your carrier, what is your</p> <p>18 business hours of operation, how many employees</p> <p>19 do you have, your power of attorneys, who can</p> <p>20 sign 222 forms. They have a binder of 66</p> <p>21 questions that are all specific to that license</p> <p>22 that they're auditing.</p> <p>23 Q. Okay. And were they typically things</p> <p>24 that you would be able to answer off the top of</p>
<p style="text-align: right;">Page 83</p> <p>1 doing their inspection, and they'd ask us for</p> <p>2 records, and we would go to our teams and get</p> <p>3 the records and bring them back. So we were</p> <p>4 considered the audit leads.</p> <p>5 Q. Okay. And who were the persons who</p> <p>6 were in the role of security manager from time</p> <p>7 to time?</p> <p>8 A. Rich Nikolaus prior to 2015, I</p> <p>9 believe, and currently Edward Egan.</p> <p>10 Q. Any other roles with respect to the</p> <p>11 DEA audits apart from this process you described</p> <p>12 of retrieving records that were requested by</p> <p>13 DEA?</p> <p>14 A. So I answered all of their questions</p> <p>15 in regards to our processes in the plant, how we</p> <p>16 handle -- facilitated the reconciliation,</p> <p>17 provided them with reports. Anytime that DEA</p> <p>18 came on-site, I was the point of contact.</p> <p>19 Whether it was for an inspection or to approve a</p> <p>20 cage or a vault or to do any type of anything on</p> <p>21 the site, I was the point of contact.</p> <p>22 Q. Okay. Does this go back to 2001 that</p> <p>23 you were the point of contact for DEA visits?</p> <p>24 A. 2001 I was what we call the back room,</p>	<p style="text-align: right;">Page 85</p> <p>1 your head, or normally are they things that you</p> <p>2 needed to go back and research?</p> <p>3 A. Most of the time I could answer them.</p> <p>4 I knew the processes, the plant inside and out</p> <p>5 and could answer most of their questions. If I</p> <p>6 couldn't, I didn't guess or speculate. I'd tell</p> <p>7 them I'd get the answer and get back to them.</p> <p>8 Q. And the DEA audit, is it a regularly</p> <p>9 scheduled event with a regular frequency, or was</p> <p>10 it just whenever they happen to tell you they're</p> <p>11 going to do it?</p> <p>12 A. They're typical actually unannounced,</p> <p>13 so it's whenever DEA shows up at our door. We</p> <p>14 need to be ever constantly ready for the DEA</p> <p>15 audit at any time, which we are.</p> <p>16 Q. Is it ordinarily done -- even though</p> <p>17 it may be unannounced, is it approximately an</p> <p>18 annual event, or is it done more frequently than</p> <p>19 that?</p> <p>20 A. The past audits have no rhyme or</p> <p>21 reason to any type of frequency.</p> <p>22 Q. Does the DEA after their audit provide</p> <p>23 you with any sort of report or their feedback as</p> <p>24 to the results of the audit?</p>

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1 A. There's never a DEA report. If they  
2 have concerns, they will discuss them with you  
3 at the time of the audit. They may direct us --  
4 they may ask us a process, and I explain it, and  
5 they go, yeah, we're not comfortable with that,  
6 we want you to do it this way. And so we always  
7 do whatever DEA directs us because they have  
8 jurisdiction over us.

9 Q. Can you recall specific examples of  
10 any sort of negative feedback you got from the  
11 DEA as to a process or other matter that came up  
12 in the course of their audit?

13 MR. O'CONNOR: Objection to form.

14 A. A negative, I'd say no. They, you  
15 know, may, well, we don't really like that, or  
16 we think you should do it this way, or it will  
17 make it -- you know, if you give us a report in  
18 this format it makes it easier for us to  
19 reconcile.

20 Negative, I don't -- I don't know what  
21 would be considered negative. Any feedback they  
22 gave us was always constructive.

23 Q. Sure. Maybe negative is a bad word.  
24 For example, you said they might from

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1 time to time say, well, we don't really like  
2 that, do it this way. Can you think of specific  
3 examples where that sort of comment came back to  
4 you?

5 A. We would stage material in our  
6 manufacturing hallway if it was getting ready to  
7 go into production within a day, and they said,  
8 well, we don't really like that, we'll let you  
9 stage it for up to a shift, so then we  
10 immediately changed all our processes that said  
11 we couldn't stage material for any longer than a  
12 shift.

13 Q. Anything else of that nature you can  
14 recall?

15 A. We wanted to store material from our  
16 manufacturing license in our distributor vault,  
17 and they said, no, they wanted us to write for a  
18 waiver. We couldn't -- it was -- it's in the  
19 regulations that we could do it, but they asked  
20 us to get a waiver on file, so we wrote for a  
21 waiver on file.

22 Q. You mentioned one of the topics that  
23 you have attended trainings on is state  
24 licensing?

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1 A. Yes.

2 Q. So in what aspects of state licensing  
3 did you have responsibility for from time to  
4 time at Mallinckrodt?

5 A. I don't have any responsibility for  
6 state licensing. I'm aware of it. I'd go to  
7 the trainings so that we're aware of any states  
8 that require us to report losses, or some states  
9 have additional reporting requirements, so we  
10 would attend the training to make sure we're  
11 aware of any individual state requirements --

12 Q. Okay.

13 A. -- that may impact the site.

14 Q. When you say "we," who else from  
15 Mallinckrodt attends those types of trainings?

16 A. It depends. So Karen Harper, my  
17 manager/director will attend, and Dave Hunter  
18 and myself will swap out. So we all can't leave  
19 all at the same time, there's got to be somebody  
20 at home, so we alternate and we'll take turns at  
21 conferences. That's why, for example, when I  
22 said the IQVIA conferences, you know, a half  
23 dozen because we alternate years of who attends.

24 Q. And how about, you indicated exports

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1 was another topic that you attend trainings on  
2 from time to time. What aspect of exports do  
3 you have responsibility for?

4 A. That I do have responsibility for  
5 applying for the 161 application to export our  
6 products, so I get the import permit from our  
7 customer service department who liaisons with  
8 our international customers, and then I file for  
9 the export permit. When the export permit is  
10 received, I notify distribution and customer  
11 service that the order can be released, we have  
12 the permits.

13 Q. And you indicated the suspicious order  
14 monitoring was one of the topics that you  
15 attended trainings on. What aspects of  
16 suspicious order monitoring do you have  
17 responsibility for?

18 A. Currently that is done by my group. I  
19 have a data analyst auditor that reports to me,  
20 and she is the primary contact for part of our  
21 suspicious order monitoring program and our  
22 anti-diversion program. She does the daily  
23 orders review.

24 Q. And who is that?



<p style="text-align: right;">Page 90</p> <p>1 A. Rachelle Rogers currently.</p> <p>2 Q. And what is the aspect of the SOM</p> <p>3 program that your team has responsibility for?</p> <p>4 A. So we review the orders that are held</p> <p>5 for review that meet the algorithm criteria, we</p> <p>6 do Google searches, we do chargeback reviews, we</p> <p>7 respond to the DEA for shipping history</p> <p>8 verifications, we're in the process of</p> <p>9 transitioning the customer checklists to Hobart,</p> <p>10 off the top of my head.</p> <p>11 Q. That customer checklist transitioning,</p> <p>12 what -- it's being transitioned from where?</p> <p>13 A. It's currently residing with the --</p> <p>14 our customer data integrity group, and we're</p> <p>15 going to be reviewing them in Hobart as opposed</p> <p>16 to out at corporate.</p> <p>17 Q. And for how long has your team had</p> <p>18 these responsibilities with respect to SOM?</p> <p>19 A. Since April of 2017.</p> <p>20 Q. So before that time, what</p> <p>21 responsibilities did you have with respect to</p> <p>22 SOM?</p> <p>23 A. I was a backup reviewer to the auditor</p> <p>24 analyst who was located in St. Louis, and I was</p>	<p style="text-align: right;">Page 92</p> <p>1 the role, what do you mean by that?</p> <p>2 A. So when the distribution center was in</p> <p>3 St. Louis, they had a program in place, and when</p> <p>4 it moved to Hobart in 2001 that program</p> <p>5 transferred over to Hobart.</p> <p>6 Q. Okay. So there was an algorithm in</p> <p>7 place from 2001 at Hobart for SOM?</p> <p>8 A. To the best of my knowledge, yes.</p> <p>9 Q. Do you recall what that algorithm</p> <p>10 consisted of in any regard going back to 2001?</p> <p>11 A. I know it had something to do with</p> <p>12 sales history, but I don't remember the exact</p> <p>13 formula.</p> <p>14 Q. Did you have an understanding of how</p> <p>15 the algorithm changed over time?</p> <p>16 A. Not really, not until I was involved</p> <p>17 in it in 2012.</p> <p>18 Q. So since 2012, has the algorithm</p> <p>19 changed?</p> <p>20 A. Yes.</p> <p>21 Q. And have you had an understanding of</p> <p>22 how it has changed since then?</p> <p>23 A. Yes.</p> <p>24 Q. And what -- tell me what you can</p>
<p style="text-align: right;">Page 91</p> <p>1 a member of the SOM team.</p> <p>2 Q. As a backup reviewer, what was your</p> <p>3 role there?</p> <p>4 A. So if the primary reviewer was on</p> <p>5 vacation or out of the office, then I would</p> <p>6 conduct -- excuse me, I would conduct the daily</p> <p>7 reviews.</p> <p>8 Q. And what do those reviews consist of?</p> <p>9 A. Orders that have gone -- orders that</p> <p>10 have met the algorithm hit and have gone on</p> <p>11 hold, to review and determine if they're</p> <p>12 appropriate to release.</p> <p>13 Q. And when did you first have that</p> <p>14 backup responsibility?</p> <p>15 A. Roughly 2012.</p> <p>16 Q. And you've made reference a couple</p> <p>17 times to the algorithm hit. When was the</p> <p>18 algorithm implemented, do you recall?</p> <p>19 A. There's always been an algorithm in</p> <p>20 place since I went into the role. We've</p> <p>21 constantly enhanced the algorithm. But the</p> <p>22 exact formula of it, I don't remember the</p> <p>23 specifics.</p> <p>24 Q. And when you say since you went into</p>	<p style="text-align: right;">Page 93</p> <p>1 recall as to how it's changed since 2012.</p> <p>2 A. Since 2012, we were initially looking</p> <p>3 at 18-month history based on the bill to, and</p> <p>4 now we're looking at the 18-month history based</p> <p>5 on the ship to.</p> <p>6 Q. And so tell me what the difference is</p> <p>7 between bill to and ship to.</p> <p>8 A. So bill to is -- a parent company is</p> <p>9 where the bills go to, but they may have</p> <p>10 distribution centers all throughout the United</p> <p>11 States, and that's the ship to. So we bill to</p> <p>12 one location but we physically ship to another</p> <p>13 location.</p> <p>14 Q. Okay. Any other changes in the</p> <p>15 algorithm since 2012 that you're aware of?</p> <p>16 A. Not that I personally am aware of.</p> <p>17 But it was overseen by corporate, so I don't</p> <p>18 know if they may have been making changes to it</p> <p>19 or not.</p> <p>20 Q. Do you have any understanding as to</p> <p>21 the reason for the change from bill to to ship</p> <p>22 to?</p> <p>23 A. Just to always make it better and</p> <p>24 thought it would be an improvement.</p>

<p style="text-align: right;">Page 94</p> <p>1 Q. You indicated that you've been a                  2 member of the SOM team. For how long have you                  3 been a member of the SOM team?                  4 A. Well, I started doing the backup                  5 reviews in 2012, but I don't think I was part of                  6 the team until '14 or '15, right around there.                  7 Q. So is the -- was the change to the                  8 algorithm that you described something that the                  9 SOM team had involvement on?                  10 A. Yes.                  11 Q. Were you involved in discussions of                  12 that change?                  13 A. Yes.                  14 Q. And what can you recall of those                  15 discussions?                  16 A. Just that we thought it would be                  17 better to see the individual distributors versus                  18 the parent company to see the amounts going to                  19 individual distributors for analysis purposes.                  20 Q. And do you recall why it was thought                  21 that that would be better?                  22 A. Initially we thought that looking at                  23 the parent company as a whole would be better,                  24 because then if a distributor was shuffling</p>	<p style="text-align: right;">Page 96</p> <p>1 drug take-back boxes in our local communities                  2 for the community to take back the unwanted                  3 medicines. It's a comprehensive program. We                  4 have disposal pouches that our government                  5 regulatory affairs department has provided to                  6 pharmacies and customers for people to dispose                  7 of unwanted opioids.                  8 Q. To your knowledge, is there someone at                  9 Mallinckrodt that has responsibility for the                  10 overall comprehensive anti-diversion program?                  11 A. We all have components of it. It's                  12 made up of different departments. I guess the                  13 overarching would be legal, corporate legal.                  14 Q. And when you use the word "diversion,"                  15 what do you mean by that?                  16 A. Something taken out of the lifecycle                  17 in the hands of where it doesn't belong.                  18 Q. When you say "lifecycle," what do you                  19 mean?                  20 A. So we use the term analogy inside of                  21 the plant where if it's not in the lifecycle, so                  22 if it's not in the process of dispensing,                  23 blending, compression or packaging, it's out of                  24 the lifecycle.</p>
<p style="text-align: right;">Page 95</p> <p>1 between their distributions we wouldn't see it                  2 if we were looking at individual distributor,                  3 but by going -- looking at each distributor,                  4 then we could see what we were directly shipping                  5 to each location.                  6 Q. You indicated that your team currently                  7 has at least some responsibility for the                  8 anti-diversion program?                  9 A. Yes.                  10 Q. And what are the responsibilities                  11 related to the anti-diversion program?                  12 A. So we answer any DEA or law                  13 enforcement requests for shipping history                  14 information through our global security                  15 director. We receive -- I may receive a request                  16 from a law enforcement agency for placebo                  17 tablets for them to use in investigations, and I                  18 will facilitate that through the global security                  19 vice president. Anything that we can do to help                  20 battle diversion if we're asked upon it. We                  21 keep up-to-date with trends so that we have                  22 knowledge and aware of what's being abused so                  23 that we can pay particular attention to any                  24 specific molecule, drugs of concern. We sponsor</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. So that lifecycle that you've                  2 described, dispensing, blending, compression or                  3 packaging, are those all things that occur in                  4 the plant?                  5 A. Yes.                  6 Q. Okay. So is diversion something that                  7 occurs in the manufacturing process, as you use                  8 the term?                  9 A. There's potential. We have to                  10 maintain effective controls to detect diversion.                  11 Q. And what controls are in place in                  12 terms of diversion in the manufacturing process?                  13 A. There's many different controls,                  14 security systems, physical securities,                  15 tamper-evident bags, seals, two-person                  16 verifications. Every department has individual                  17 procedures based on their exposure and                  18 processing step.                  19 Q. Okay. And then is there diversion                  20 that can occur after the product leaves the                  21 manufacturing facility?                  22 A. Out of our hands?                  23 Q. Yes.                  24 A. I would say yes, there's a lot of</p>



<p style="text-align: right;">Page 98</p> <p>1 opportunity for that.</p> <p>2 Q. Okay. And some of the anti-diversion</p> <p>3 steps that you described, for example placebo</p> <p>4 tablets, to law enforcement, that would be</p> <p>5 related to diversion that's occurring after the</p> <p>6 product leaves your manufacturing facility,</p> <p>7 right?</p> <p>8 A. Yes.</p> <p>9 Q. And so diversion in that sense after</p> <p>10 it's left the manufacturing facility, when you</p> <p>11 use the term diversion in that context, what</p> <p>12 does it mean to you?</p> <p>13 A. Not where it belongs.</p> <p>14 Q. And you're aware that the</p> <p>15 litigation -- I realize you haven't read any of</p> <p>16 the operative complaints, but you're aware that</p> <p>17 the litigation in large part pertains to various</p> <p>18 opioids that have, to use your term, wound up</p> <p>19 not where they belong, correct?</p> <p>20 A. Yes.</p> <p>21 Q. And you're aware that that's become a</p> <p>22 serious problem over the last period of time,</p> <p>23 correct?</p> <p>24 MR. O'CONNOR: Objection to form.</p>	<p style="text-align: right;">Page 100</p> <p>1 2012.</p> <p>2 BY MR. GOTTO:</p> <p>3 Q. Do you recall any time at Mallinckrodt</p> <p>4 receiving any -- well, during the period that</p> <p>5 you reported to Ms. Harper, was there any --</p> <p>6 ever a time when Ms. Harper communicated to you</p> <p>7 that -- a belief that diversion was a serious</p> <p>8 problem?</p> <p>9 MR. O'CONNOR: Objection to form.</p> <p>10 A. She may have. I don't remember any</p> <p>11 specifically.</p> <p>12 BY MR. GOTTO:</p> <p>13 Q. Okay. Do you recall anyone else at</p> <p>14 Mallinckrodt at any point communicating to you a</p> <p>15 belief that diversion was a serious problem?</p> <p>16 MR. O'CONNOR: Objection to form.</p> <p>17 A. I remember potentially Bill Ratliff,</p> <p>18 who was the security director at the time,</p> <p>19 raising the concern.</p> <p>20 BY MR. GOTTO:</p> <p>21 Q. Okay. In what context can you recall</p> <p>22 that?</p> <p>23 A. Not specifics.</p> <p>24 Q. Do you recall the approximate time</p>
<p style="text-align: right;">Page 99</p> <p>1 A. Yes.</p> <p>2 BY MR. GOTTO:</p> <p>3 Q. When do you recall first being aware</p> <p>4 that the diversion of opioids was a serious</p> <p>5 problem?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. I don't remember exactly when I --</p> <p>8 when it started occurring to me.</p> <p>9 BY MR. GOTTO:</p> <p>10 Q. Okay. When you -- in 2001 when you</p> <p>11 first had responsibility in compliance, did you</p> <p>12 view diversion of opioids at that point as a</p> <p>13 serious problem?</p> <p>14 MR. O'CONNOR: Same objection.</p> <p>15 A. In 2001?</p> <p>16 BY MR. GOTTO:</p> <p>17 Q. Uh-huh.</p> <p>18 A. No, I wasn't aware of it at that time.</p> <p>19 Q. How about in 2012 when you indicated</p> <p>20 you became a member of the SOM team, at that</p> <p>21 point did you view diversion as a serious</p> <p>22 problem?</p> <p>23 MR. O'CONNOR: Objection.</p> <p>24 A. I don't recall if I did or not in</p>	<p style="text-align: right;">Page 101</p> <p>1 frame?</p> <p>2 A. No. There was a lot going on.</p> <p>3 Q. You indicated that Mallinckrodt has a</p> <p>4 comprehensive program to try to address</p> <p>5 diversion, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And so let's just talk about some of</p> <p>8 the components of that. One of them you</p> <p>9 indicated was providing placebo tablets to law</p> <p>10 enforcement, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And do you recall when that began?</p> <p>13 A. Approximately 2016.</p> <p>14 Q. And you indicated that one of the</p> <p>15 things that's done with respect to diversion is</p> <p>16 to keep up-to-date on what the drugs of concern</p> <p>17 are, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And I take it in that sense you mean</p> <p>20 concern to law enforcement?</p> <p>21 A. Yes, and to DEA. DEA uses the</p> <p>22 terminology drugs of concern.</p> <p>23 Q. Okay. And do you do anything</p> <p>24 personally to stay up-to-date on what the drugs</p>

<p style="text-align: right;">Page 102</p> <p>1 of concern are?</p> <p>2 A. I read the DEA's web page frequently.</p> <p>3 The auditor analyst in our team does social</p> <p>4 media reviews. We benchmark amongst our team</p> <p>5 members between Webster group, St. Louis, and</p> <p>6 Hobart. If somebody sees an article that's of</p> <p>7 concern, they'll share that article so that we</p> <p>8 can keep up-to-date with what's going on.</p> <p>9 Q. Okay. And this process of being</p> <p>10 up-to-date on drugs of concern, when did that</p> <p>11 begin, at least as far as your own involvement</p> <p>12 in it?</p> <p>13 A. With the DEA conferences, that's where</p> <p>14 we would hear that terminology, and they'd say</p> <p>15 they're paying particular attention to</p> <p>16 hydrocodone because it's a drug of concern.</p> <p>17 That was a comment when the quota reviews were</p> <p>18 taking an extended amount of time, industry was</p> <p>19 asking DEA why it's taking so long, and they</p> <p>20 said they were paying particular attention to</p> <p>21 drugs of concern.</p> <p>22 Q. And when you're aware of a drug being</p> <p>23 identified as a drug of concern from time to</p> <p>24 time, what steps would that trigger at</p>	<p style="text-align: right;">Page 104</p> <p>1 were concerned about Codeine because that would</p> <p>2 remain a 3, and they were concerned that that</p> <p>3 would start replacing the hydrocodone. Most</p> <p>4 recent conference a couple years ago, they said</p> <p>5 hydromorphone 8-milligram was starting to be</p> <p>6 abused.</p> <p>7 Q. And so the drugs that you can recall</p> <p>8 being identified as drugs of concern, were they</p> <p>9 all drugs that Mallinckrodt manufactured?</p> <p>10 A. Yes.</p> <p>11 Q. And were they all drugs that</p> <p>12 Mallinckrodt had a significant market share at</p> <p>13 least of generics?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. I don't know, have any details on</p> <p>16 market share.</p> <p>17 BY MR. GOTTO:</p> <p>18 Q. Okay. Were you aware from time to</p> <p>19 time that Mallinckrodt was a leading</p> <p>20 manufacturer of many of the opioid drugs of</p> <p>21 concern that were identified from time to time?</p> <p>22 MR. O'CONNOR: Objection to form.</p> <p>23 A. No specific details. I had heard, you</p> <p>24 know, our site director refer to us as being one</p>
<p style="text-align: right;">Page 103</p> <p>1 Mallinckrodt with respect to that particular</p> <p>2 drug?</p> <p>3 A. Nothing different. We would still do</p> <p>4 all of our same processes that we always have</p> <p>5 done, it's just we were more responsive to a</p> <p>6 molecule that may be more susceptible to</p> <p>7 diversion.</p> <p>8 Q. So more sensitive to it, but how does</p> <p>9 that sensitivity manifest itself in any</p> <p>10 particular action?</p> <p>11 A. We may escalate quicker if we see a</p> <p>12 problem, or if I get a call from a law</p> <p>13 enforcement and they've expressed that they had</p> <p>14 a drug bust and it was of oxycodone, I would</p> <p>15 make sure that our security director and global</p> <p>16 VP were aware of it so that they could reach out</p> <p>17 and assist to the best of our ability.</p> <p>18 Q. So what drugs can you recall being</p> <p>19 identified as drugs of concern? You've already</p> <p>20 mentioned hydrocodone. What other ones can you</p> <p>21 recall?</p> <p>22 A. Hydrocodone, oxycodone. When DEA</p> <p>23 rescheduled hydrocodone from a C3 to a C2, they</p> <p>24 had said at one of their conferences that they</p>	<p style="text-align: right;">Page 105</p> <p>1 of the top manufacturers, but I didn't have</p> <p>2 firsthand knowledge of that.</p> <p>3 BY MR. GOTTO:</p> <p>4 Q. You've heard reference to an opioid</p> <p>5 epidemic in this country, correct?</p> <p>6 A. Yes.</p> <p>7 Q. When do you first recall being aware</p> <p>8 that there was an opioid epidemic?</p> <p>9 MR. O'CONNOR: Objection to form.</p> <p>10 A. I don't remember the exact time frame.</p> <p>11 BY MR. GOTTO:</p> <p>12 Q. Is it something that you can recall</p> <p>13 receiving any information from others at</p> <p>14 Mallinckrodt about?</p> <p>15 A. No.</p> <p>16 Q. You'd agree that certain prescription</p> <p>17 opioids manufactured by Mallinckrodt have been</p> <p>18 diverted over the years, wouldn't you?</p> <p>19 MR. O'CONNOR: Objection to form.</p> <p>20 A. Yes.</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. And you would agree that certain</p> <p>23 opioids manufactured by Mallinckrodt have</p> <p>24 contributed to the opioid epidemic, wouldn't</p>

<p style="text-align: right;">Page 106</p> <p>1 you?</p> <p>2 MR. O'CONNOR: Objection to form.</p> <p>3 A. I don't know that.</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. You indicated that one of the -- one</p> <p>6 of your responsibilities has been to learn about</p> <p>7 applicable regulations that apply to the Hobart</p> <p>8 facility's manufacturing and distribution</p> <p>9 licenses, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And do those include requirements to</p> <p>12 design and maintain a suspicious order</p> <p>13 monitoring program?</p> <p>14 A. Yes.</p> <p>15 Q. And so when did you first become</p> <p>16 familiar with those regulatory requirements?</p> <p>17 A. So I knew that there was a system in</p> <p>18 place that was being reviewed out at corporate</p> <p>19 in the early 2000s, and then I recall the</p> <p>20 letters to industry as calling it out</p> <p>21 specifically.</p> <p>22 Q. The letters from Mr. Rannazzisi?</p> <p>23 A. Yes, from DEA.</p> <p>24 Q. Did you receive those letters when</p>	<p style="text-align: right;">Page 108</p> <p>1 A. No, just the early 2000s. I wouldn't</p> <p>2 want to guess. I can't remember exactly.</p> <p>3 Q. All right. What would you do when</p> <p>4 there was an algorithm hit that -- you indicated</p> <p>5 you would review it through customer service.</p> <p>6 What were the specific steps you would take?</p> <p>7 MR. O'CONNOR: Objection to form.</p> <p>8 A. So if the order was -- on the list was</p> <p>9 a clinic, and it was a higher than -- order than</p> <p>10 they had been ordering historically, I would</p> <p>11 contact customer service, because they had the</p> <p>12 contacts with the customer, and say can you find</p> <p>13 out why this customer has ordered X number of</p> <p>14 bottles. And very commonly they would come back</p> <p>15 and they would say, well, the customer is moving</p> <p>16 and they ordered a double order to get them</p> <p>17 through until they get to their new location and</p> <p>18 their new 222 forms, or they were part of a</p> <p>19 chain and one of their other sister clinics</p> <p>20 closed so they were taking on those patients.</p> <p>21 And then I would write on the list of why, and</p> <p>22 I'd file it.</p> <p>23 Q. When you use the term "algorithm hit,"</p> <p>24 are you familiar with the term "peculiar order"?</p>
<p style="text-align: right;">Page 107</p> <p>1 they went out?</p> <p>2 A. We received two of them. There was a</p> <p>3 third one that we didn't receive, like corporate</p> <p>4 had it from some avenue.</p> <p>5 Q. Okay. So you were aware of corporate</p> <p>6 review in the early 2000s. In terms of your --</p> <p>7 any personal involvement you had or</p> <p>8 responsibility that pertained to Mallinckrodt's</p> <p>9 regulatory obligation to design and maintain an</p> <p>10 effective SOM program, when did you first have</p> <p>11 any personal responsibility in that regard?</p> <p>12 A. So a transition between Hobart and</p> <p>13 corporate a few times. There was a period, I</p> <p>14 don't remember the exact years, early 2000s, of</p> <p>15 which I would review the orders that were</p> <p>16 algorithm hits, and if need be get additional</p> <p>17 information through customer service. And then</p> <p>18 there was a point in time where it had</p> <p>19 transitioned back to corporate and was being</p> <p>20 reviewed at the corporate level.</p> <p>21 Q. So when you -- during the period of</p> <p>22 time when you had responsibility to review the</p> <p>23 orders that were algorithm hits, any</p> <p>24 approximation what that time period is?</p>	<p style="text-align: right;">Page 109</p> <p>1 A. I've heard of that before.</p> <p>2 Q. Okay. Was that a term that was part</p> <p>3 of the Mallinckrodt SOM process at some point?</p> <p>4 A. Yes.</p> <p>5 Q. And so was an algorithm hit, as you've</p> <p>6 used that term, the same thing as an order that</p> <p>7 was identified as a peculiar order?</p> <p>8 A. Could be, yes.</p> <p>9 Q. And so if an algorithm hit order was</p> <p>10 provided to you, or you became aware of it for</p> <p>11 SOM purposes, and you went through customer</p> <p>12 service and got an explanation and you noted</p> <p>13 what that explanation was, what would happen</p> <p>14 after that with respect to that particular</p> <p>15 order?</p> <p>16 A. It would be released.</p> <p>17 Q. It would be filled?</p> <p>18 A. No. I apologize. So at that time</p> <p>19 these were excessive order reports, so it had</p> <p>20 already been shipped, and I was reviewing the</p> <p>21 orders after they had been shipped.</p> <p>22 Q. Okay. So what would happen? Would</p> <p>23 anything happen after that, once you got the</p> <p>24 response back from customer service and you</p>

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1 noted whatever the response was that you  
2 received? Would anything further happen with  
3 that order?  
4 A. Those reports were sent to DEA. With  
5 that order, no, nothing further would happen  
6 with that order.  
7 Q. Okay. But the -- there was a report  
8 sent to the DEA?  
9 A. Mm-hmm.  
10 Q. And what was the nature of that  
11 report? Was it a regular monthly report, or was  
12 it a particular report with respect to each  
13 order?  
14 MR. O'CONNOR: Objection to form.  
15 A. I don't remember if it was monthly or  
16 quarterly, but it was a PDF that was sent to DEA  
17 and what DEA classified and categorized as  
18 excessive order reports.  
19 BY MR. GOTTO:  
20 Q. Okay. And was -- were you the person  
21 who submitted those reports to DEA?  
22 A. Yes, at that time.  
23 Q. And again, do you have a time frame in  
24 mind when this was the applicable procedure?

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1 A. No. I remember doing it early in my  
2 career, and then it was transferred out to  
3 St. Louis, out to corporate, and I -- that's why  
4 I say early 2000s. It was the early part of my  
5 career, but I don't remember the exact time.  
6 Q. Okay. So --  
7 A. May I be excused?  
8 Q. Yes.  
9 MR. GOTTO: Let's go off the record.  
10 THE VIDEOGRAPHER: The time is  
11 11:26 a.m., and we're off the record.  
12 (Whereupon, a recess was taken.)  
13 THE VIDEOGRAPHER: The time is  
14 11:40 a.m., and we're on the record.  
15 (Whereupon, Mallinckrodt-Spaulding-1  
16 was marked for identification.)  
17 BY MR. GOTTO:  
18 Q. Ms. Spaulding, we've handed you a  
19 document that we marked as Exhibit 1 bearing  
20 Bates MNK-T1\_0000278740, appears to be an e-mail  
21 from Karen Harper to you dated 11/11/09  
22 concerning your goal.  
23 Would you please take a moment to look  
24 at that e-mail?

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1 A. Okay.  
2 Q. Do you recognize that e-mail?  
3 A. No.  
4 Q. Did you annually establish goals that  
5 you would -- you and Ms. Harper establish what  
6 your goals would be for the upcoming year?  
7 A. Yes.  
8 Q. Any reason to think that this e-mail  
9 does not accurately describe what your goals are  
10 for 2010?  
11 A. No.  
12 Q. Okay. And among those goals, you'll  
13 see it indicates "Continue implementation and  
14 ongoing upgrades of the Suspicious Order  
15 Monitoring Program by second quarter fiscal year  
16 '10"?  
17 A. Yes.  
18 Q. And the fiscal here at Mallinckrodt  
19 ends when?  
20 A. At this time our fiscal year was  
21 October 1 through September 30 -- 30.  
22 Q. Okay. So the fiscal year 2010 would  
23 be the year ending September 30, 2010?  
24 A. Yes.

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1 Q. And so the second quarter of that year  
2 would have been ending on March 31, 2010, is  
3 that right?  
4 A. Yes.  
5 Q. Do you recall what the implementation  
6 and ongoing upgrades tasks were that you -- that  
7 your goal included for fiscal year 2010?  
8 A. No.  
9 Q. Fair to say that at this point you  
10 would have had an understanding of at least some  
11 aspects of the SOM program at this time,  
12 correct?  
13 A. Some aspects, yes.  
14 Q. Had you had responsibility for  
15 implementation for upgrade of any aspect of the  
16 SOM program for fiscal year 2009?  
17 A. I don't remember.  
18 Q. And do you have any recollection of  
19 upgrades that you were involved in considering  
20 in fiscal year 2010?  
21 A. No, not any specifics.  
22 Q. Do you have any recollection as to any  
23 aspects of the SOM program that Ms. Harper  
24 indicated to you required upgrading in this time

<p style="text-align: right;">Page 114</p> <p>1 frame?</p> <p>2 MR. O'CONNOR: Objection to form.</p> <p>3 A. Can you restate that, please?</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. Yes.</p> <p>6 Do you have any recollection of</p> <p>7 Ms. Harper in this time frame indicating to you</p> <p>8 that there were any particular aspects of the</p> <p>9 SOM program that required upgrading?</p> <p>10 A. I don't remember the specifics, no.</p> <p>11 Q. Do you have a general understanding of</p> <p>12 what required upgrading?</p> <p>13 A. No.</p> <p>14 Q. Do you recall if there was a written</p> <p>15 SOM program at this point?</p> <p>16 A. What do you mean by "written"?</p> <p>17 Q. Well, was there a SOM program that was</p> <p>18 memorialized in any sort of document?</p> <p>19 A. Oh, an SOP?</p> <p>20 Q. Well, or any sort of document.</p> <p>21 A. Not at this time. I don't remember</p> <p>22 what was in place at this time.</p> <p>23 Q. Okay. You don't recall one way or the</p> <p>24 other whether there was a written program or</p>	<p style="text-align: right;">Page 116</p> <p>1 '10 Assessment.</p> <p>2 Would you take a look at that document</p> <p>3 and tell me if you recognize it?</p> <p>4 (Witness reviewing document.)</p> <p>5 A. This is my year-end review for fiscal</p> <p>6 year '10.</p> <p>7 Q. Okay. Did you receive a similar</p> <p>8 review each year?</p> <p>9 A. There's a review done each year, it's</p> <p>10 not -- it's a different software program, but</p> <p>11 yes, there's a review done each year.</p> <p>12 Q. Okay. If you would turn to the page</p> <p>13 that's numbered 5, it ends in Bates 708. And</p> <p>14 the Performance Factor or Target Competency is</p> <p>15 "DEA Reports."</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And in the Expected Results</p> <p>19 paragraph, the last sentence says "Continue</p> <p>20 implementation and ongoing upgrades of the</p> <p>21 Suspicious Order Monitoring Program by second</p> <p>22 quarter fiscal year '10."</p> <p>23 That's what we had seen in the prior</p> <p>24 document, correct, your goals for fiscal year</p>
<p style="text-align: right;">Page 115</p> <p>1 not?</p> <p>2 A. I don't.</p> <p>3 Q. Do you recall working with anyone in</p> <p>4 fiscal year '10 on the implementation and</p> <p>5 upgrading of the SOM?</p> <p>6 A. In fiscal year '10. I know there was</p> <p>7 a review of the program done. I don't know what</p> <p>8 year it was.</p> <p>9 Q. Okay. Who can you recall being</p> <p>10 involved in that review?</p> <p>11 A. Karen Harper.</p> <p>12 Q. Anyone else?</p> <p>13 A. There would have been other</p> <p>14 stakeholders of the business, but I don't</p> <p>15 remember the specific people.</p> <p>16 Q. And you don't recall what the time</p> <p>17 frame was of that review?</p> <p>18 A. No.</p> <p>19 (Whereupon, Mallinckrodt-Spaulding-2</p> <p>20 was marked for identification.)</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. We've handed you what we've marked as</p> <p>23 Exhibit 2, a multi-page document beginning at</p> <p>24 MNK-T1_0000490704, appears to be a Fiscal Year</p>	<p style="text-align: right;">Page 117</p> <p>1 '10?</p> <p>2 A. Yes.</p> <p>3 Q. Now, that was -- was that upgrade</p> <p>4 accomplished in fiscal year '10?</p> <p>5 A. I don't remember what the upgrade was</p> <p>6 to know whether it was completed that year or</p> <p>7 not.</p> <p>8 Q. So in your "End-of-Year</p> <p>9 Accomplishments (Employee)" paragraph, the last</p> <p>10 sentence indicates "Continuing to assist and</p> <p>11 implement upgrades on the SOM when identified</p> <p>12 along with generation of a quarterly report to</p> <p>13 DEA."</p> <p>14 Do you see that?</p> <p>15 A. No. I'm sorry. Which one? Under</p> <p>16 that same one?</p> <p>17 Q. Sure. Yes, "End-of-year</p> <p>18 Results/Accomplishments (Employee)," the</p> <p>19 paragraph that begins "All controlled substance</p> <p>20 reports."</p> <p>21 A. Okay. My -- that was my feedback.</p> <p>22 Okay. I'm sorry.</p> <p>23 Q. It's the last sentence of that</p> <p>24 paragraph.</p>



<p style="text-align: right;">Page 118</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And then if you look at the</p> <p>3 following paragraph "End-of-Year</p> <p>4 Results/Accomplishments (Manager)," would that</p> <p>5 have been Ms. Harper preparing that?</p> <p>6 A. Yes. So the employee was my -- my</p> <p>7 review of my work throughout the year, and then</p> <p>8 the next one was Karen's, yes.</p> <p>9 Q. Okay. And under the manager</p> <p>10 paragraph, the last sentence reads "Eileen</p> <p>11 volunteered for extra responsibility within the</p> <p>12 Suspicious Order Monitoring Program in fiscal</p> <p>13 year '10, enhancements to the system and</p> <p>14 expansion of Eileen's role will be accomplished</p> <p>15 in fiscal year '11."</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. And so does that indicate that the --</p> <p>19 whatever the upgrades were that were the subject</p> <p>20 of your goal for fiscal year '10 were not</p> <p>21 actually implemented in fiscal year '10,</p> <p>22 correct?</p> <p>23 MR. O'CONNOR: Objection to form.</p> <p>24 A. I don't know that.</p>	<p style="text-align: right;">Page 120</p> <p>1 submitted to DEA.</p> <p>2 Q. And so was that a report you were</p> <p>3 submitting in fiscal year 2010?</p> <p>4 A. I don't remember. "When identified</p> <p>5 along with generation of quarterly report."</p> <p>6 Q. Well, you make reference under your</p> <p>7 accomplishments to generation of a quarterly</p> <p>8 report to DEA, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And that quarterly report would be the</p> <p>11 algorithm hit or peculiar order hit report that</p> <p>12 you testified to earlier today, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Do you know if any orders were</p> <p>15 identified as suspicious orders in fiscal year</p> <p>16 2010 by Mallinckrodt?</p> <p>17 A. No, I don't know.</p> <p>18 Q. Can you recall at any time during your</p> <p>19 time at Mallinckrodt an order being reported to</p> <p>20 the DEA by Mallinckrodt as a suspicious order?</p> <p>21 A. Yes.</p> <p>22 Q. When can you recall that?</p> <p>23 A. I don't know when it was for. I don't</p> <p>24 know when it was reported.</p>
<p style="text-align: right;">Page 119</p> <p>1 BY MR. GOTTO:</p> <p>2 Q. Okay. Well, there's nothing either in</p> <p>3 your -- the employee end-of-year</p> <p>4 results/accomplishments or the manager</p> <p>5 end-of-year accomplishments that indicates that</p> <p>6 those upgrades were completed in 2010, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And the manager comments indicate that</p> <p>9 there will be enhancements and expansion of your</p> <p>10 role accomplished in fiscal year '11 -- 2011,</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. Do you recall what those enhancements</p> <p>14 to the system or expansion of your role were in</p> <p>15 2011?</p> <p>16 A. No.</p> <p>17 Q. Under the paragraph -- the employee</p> <p>18 feedback paragraph, at the very end there's</p> <p>19 reference to quarterly report to the DEA.</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. What was that quarterly report?</p> <p>23 A. So that was the algorithm hits for</p> <p>24 each month combined by quarter and then</p>	<p style="text-align: right;">Page 121</p> <p>1 Q. Do you recall any details about the</p> <p>2 order?</p> <p>3 A. Yes, it was for fentanyl that was</p> <p>4 going to a veterinary clinic or a veterinarian.</p> <p>5 Q. Okay. And was this a single incident?</p> <p>6 A. That I was aware of. I don't -- there</p> <p>7 was others that were part of the program, and</p> <p>8 monitoring, they may have reported.</p> <p>9 Q. Okay. As far as your own personal</p> <p>10 knowledge, you're only aware of the one, right?</p> <p>11 A. Yes.</p> <p>12 Q. And in terms of have you heard of</p> <p>13 others at Mallinckrodt -- other than things</p> <p>14 you've had personal involvement with, have you</p> <p>15 heard of other orders that Mallinckrodt reported</p> <p>16 to DEA as suspicious orders?</p> <p>17 A. I don't recall.</p> <p>18 Q. Okay.</p> <p>19 (Whereupon, Mallinckrodt-Spaulding-3</p> <p>20 was marked for identification.)</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. We've marked as Exhibit 3 a two-page</p> <p>23 document bearing a Bates MNK-T1_000702654.</p> <p>24 Would you take a moment to look at those</p>



<p style="text-align: right;">Page 122</p> <p>1 e-mails, please?</p> <p>2 (Witness reviewing document.)</p> <p>3 A. Okay.</p> <p>4 Q. Do you recognize those e-mails?</p> <p>5 A. No.</p> <p>6 Q. Okay. These refer to a midyear</p> <p>7 assessment done in April of 2011, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Was that a normal process at</p> <p>10 Mallinckrodt, that you would receive a midyear</p> <p>11 assessment of your performance?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. The e-mail from Ms. Harper on</p> <p>14 April 7th of 2011 indicates that you took the</p> <p>15 lead in auditing Cedardale distributor after the</p> <p>16 program identified that customer as distributing</p> <p>17 excessive amounts of oxycodone into the State of</p> <p>18 Florida, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And that you proofread and edited the</p> <p>21 three revised SOPs related to SOM, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Do you recall the Cedardale audit</p> <p>24 that's referred to?</p>	<p style="text-align: right;">Page 124</p> <p>1 just show up? How did it come to be?</p> <p>2 A. It was scheduled.</p> <p>3 Q. And how did you know what procedures</p> <p>4 to follow in conducting that audit?</p> <p>5 A. So what our process was, or -- so we</p> <p>6 -- just through conducting audits, learning from</p> <p>7 DEA what were drugs of concern, we went and</p> <p>8 reviewed their SOM program.</p> <p>9 Q. Okay. Well, let me back up.</p> <p>10 Had you conducted other audits of</p> <p>11 distributors prior to this one?</p> <p>12 A. No.</p> <p>13 Q. Okay. And had you participated in any</p> <p>14 audits of distributors prior to this one?</p> <p>15 A. I hadn't participated in on-site</p> <p>16 audits, no.</p> <p>17 Q. Okay. So how did you know what to do</p> <p>18 as part of the audit if you hadn't done one</p> <p>19 before or participated in an on-site audit?</p> <p>20 A. So we had -- we've had collaboration</p> <p>21 calls with distributors that I had been on, and</p> <p>22 had heard the questions that the compliance</p> <p>23 manager and the security director from corporate</p> <p>24 had been asking. We had a checklist that we</p>
<p style="text-align: right;">Page 123</p> <p>1 A. Yes.</p> <p>2 Q. What can you recall about that audit?</p> <p>3 A. The security manager and myself went</p> <p>4 to Cedardale in New Jersey to perform an on-site</p> <p>5 audit of their -- it's more a collaboration</p> <p>6 visit just to review their SOM program.</p> <p>7 Q. And what triggered that audit?</p> <p>8 A. A report that Karen had in which she</p> <p>9 saw a high amount of oxycodone, or the team saw</p> <p>10 a high amount of oxycodone going into the State</p> <p>11 of Florida.</p> <p>12 Q. Okay. And who was the security</p> <p>13 manager who performed that audit with you?</p> <p>14 A. Rich Nikolaus.</p> <p>15 Q. And I take it that was an on-site</p> <p>16 audit of Cedardale's facility?</p> <p>17 A. Yes.</p> <p>18 Q. Had you been to that facility</p> <p>19 previously?</p> <p>20 A. No.</p> <p>21 Q. Had you had any interaction with the</p> <p>22 people at Cedardale prior to your audit?</p> <p>23 A. No.</p> <p>24 Q. Was the audit scheduled, or did you</p>	<p style="text-align: right;">Page 125</p> <p>1 used to prompt questions. We knew what our own</p> <p>2 program was at the time. We had gone to</p> <p>3 trainings and had -- from DEA and who had said</p> <p>4 from the pulpit that, for example, thresholds</p> <p>5 are not acceptable as a stand-alone SOM program,</p> <p>6 that's not an indicator of a good program if</p> <p>7 it's only based on threshold quantities.</p> <p>8 Q. What does that mean, threshold</p> <p>9 quantities?</p> <p>10 A. So a certain limit, they can order up</p> <p>11 to X amount, and then after that amount, say,</p> <p>12 per month, the first and the next month they</p> <p>13 could order that amount again.</p> <p>14 Q. Okay. Were there particular concerns</p> <p>15 regarding Cedardale that you wanted to be sure</p> <p>16 you addressed as part of this audit?</p> <p>17 A. Well, as a result of whatever the team</p> <p>18 had discovered, we were wanting to confirm if</p> <p>19 they did, in fact, have large amount of</p> <p>20 oxycodone going into Florida.</p> <p>21 Q. Okay. And so what steps did you take</p> <p>22 to try to confirm that?</p> <p>23 A. We just spoke to them. It was all</p> <p>24 reliable -- relied on them describing. We</p>

<p style="text-align: right;">Page 126</p> <p>1 didn't review their records or their policies.  2 We'd ask them if they had policies in place, but  3 we didn't approve or condone or authorize an SOM  4 program.  5 Q. Okay. Did you -- did they have a  6 written SOM program that you reviewed?  7 A. Not that I can recall.  8 Q. But they described to you what their  9 SOM program was?  10 A. Yes.  11 Q. And what can you recall the  12 description?  13 A. That it was primarily based on these  14 threshold quantities which DEA had said from the  15 pulpit was not sufficient enough.  16 Q. Okay. And so when you can recall DEA  17 saying that the threshold quantity approach was  18 not sufficient, did they give any indication of  19 what additional components an SOM program should  20 contain beyond threshold quantities?  21 A. No. There's been very lack of  22 guidance from DEA around suspicious order  23 monitoring and what is good and what is not  24 good. They would tell us things to be aware of</p>	<p style="text-align: right;">Page 128</p> <p>1 non-controls, their amount of cash versus  2 non-cash, their demographics around the area to  3 know whether the quantities that they're  4 shipping to the pharmacy are justified or not.  5 Q. In the audit you did of Cedardale, did  6 you take any steps to identify who any specific  7 customers of Cedardale were?  8 A. I don't remember if we had specific  9 names or not.  10 Q. I take it that the focus of the audit  11 was this question of whether Cedardale was  12 distributing excessive oxycodone to Florida,  13 correct?  14 A. Yes, because we're concerned about our  15 direct customers, and we were trying to make  16 sure they had a robust program in place.  17 Q. Okay. At this time -- well, let me  18 ask you, do you recall when the Cedardale audit  19 was conducted?  20 A. Early 2011.  21 Q. Okay. At that time did you have any  22 information with respect to the identity of any  23 of Cedardale's customers?  24 A. I don't remember if I did or didn't.</p>
<p style="text-align: right;">Page 127</p> <p>1 such as red flags, but they wouldn't tell us  2 what makes a good program or what doesn't make a  3 good program, only to be aware of.  4 Q. Okay. So when you conducted the audit  5 at Cedardale, their SOM program as they  6 described it to you simply consisted of this  7 kind of threshold quantity limit that DEA had  8 specifically said was inadequate, is that fair?  9 A. Yes.  10 MR. O'CONNOR: Objection to form.  11 A. Yes.  12 BY MR. GOTTO:  13 Q. Okay. And did you tell them that,  14 that your understanding from DEA was that that  15 was not an adequate?  16 A. We did coach them in that they should  17 have more around their program than just a  18 threshold quantity amount, and that they should  19 be looking at their pharmacies holistically in  20 doing on-site inspections. It was a  21 recommendation.  22 Q. When you say "looking at a pharmacy  23 holistically," what do you mean by that?  24 A. Their amount of controls versus</p>	<p style="text-align: right;">Page 129</p> <p>1 Q. Do you recall at any point seeing any  2 reports of analysis of chargeback data that  3 contained information with respect to the  4 ultimate -- with respect to the customers of  5 Mallinckrodt's customers in 2010 or 2011?  6 A. I remember that there was three  7 customers that we as an SOM team decided that  8 needed to be audited. I don't remember the  9 specifics behind it.  10 Q. Okay. Do you remember who those three  11 customers were?  12 A. Masters and KeySource in Cedardale.  13 Q. Do you recall seeing a report at any  14 time in 2010 that identified customers who  15 ordered controlled substances from multiple  16 Mallinckrodt distributors?  17 A. No.  18 Q. Do you recall being aware of the  19 existence of such a report?  20 A. Yes. I think there was something that  21 prompted the team to review those three  22 customers.  23 Q. And do you know if that report  24 regarding customers that ordered from multiple</p>

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1 Mallinckrodt distributors, do you know if that  
2 was generated through an analysis of chargeback  
3 data?  
4 A. I don't. Don't remember.  
5 Q. Do you know who Kate Mellencamp was,  
6 or Kate Neely? I think it was the same person.  
7 A. Yeah, I remember the name. I don't  
8 remember the role.  
9 Q. Okay. How about Ginger Collier?  
10 A. Yes, Ginger I remember.  
11 Q. And who was she?  
12 A. She was in marketing.  
13 Q. Do you recall if Ms. Collier or  
14 Ms. Mellencamp had any role in developing this  
15 report on multiple orders from multiple  
16 distributors?  
17 MR. O'CONNOR: Objection to form.  
18 A. I don't remember specifically  
19 anything.  
20 BY MR. GOTTO:  
21 Q. Okay. And so when you conducted the  
22 audit at Cedardale, were you aware of whether  
23 any of Cedardale's customers had been identified  
24 as parties who ordered from multiple

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1 Mallinckrodt distributors?  
2 A. I don't remember anything about  
3 knowing their pharmacies, knowing who they were  
4 supplying.  
5 Q. What was the -- what can you recall  
6 about the results of the Cedardale audit?  
7 A. I remember that we were not  
8 comfortable that they had a robust enough  
9 program in place.  
10 Q. Okay. And as a result, was Cedardale  
11 cut off from -- as a Mallinckrodt distributor?  
12 A. I recall that they were -- we stopped  
13 shipping to them. I don't recall if it was  
14 before the audit or not, or a result of the  
15 audit.  
16 Q. And do you know if Mallinckrodt ever  
17 resumed shipping to Cedardale after that?  
18 A. I believe we did with some  
19 restrictions.  
20 Q. Do you know what the restrictions  
21 were?  
22 A. C3 through 5 only. We didn't resume  
23 shipping C2s.  
24 Q. Exhibit 2 also indicates -- I'm sorry,

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1 3, not 2, 3 indicates that you proofread and  
2 edited the three revised SOPs related to SOM.  
3 And again, this is April, 2011. Do you recall  
4 those three revised SOPs?  
5 A. Not which specific SOPs they are.  
6 Q. Do you recall the subject matter of  
7 what was addressed in any of those -- by any of  
8 those revised SOPs?  
9 A. Well, we have three SOPs that apply to  
10 suspicious order monitoring. I'm not sure that  
11 those are the three SOPs that we're talking  
12 about.  
13 Q. So the SOPs that apply to SOM, what  
14 are the subject matters that they cover?  
15 A. One, how to do the review of the  
16 algorithm hits. And I don't remember exactly  
17 what the other two are, not definitely.  
18 Q. And when did these SOPs come into  
19 existence, as far as you know?  
20 A. They were drafted by the SOM team and  
21 reviewed, so whenever that team took it back  
22 from Hobart and was reviewing the program. I  
23 don't remember. It was before 2011, obviously,  
24 but I don't remember when.

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1 Q. Okay.  
2 (Whereupon, Mallinckrodt-Spaulding-4  
3 was marked for identification.)  
4 BY MR. GOTTO:  
5 Q. We've marked as Exhibit 4 a multi-page  
6 document beginning at Bates MNK-T1\_0007730928.  
7 Appears to be an e-mail thread from 2013 between  
8 you and Ms. Harper. Would you take a moment to  
9 look at that, and tell me if you recognize it.  
10 (Witness reviewing document.)  
11 Q. Feel free to look at whatever you  
12 want, my only question is on the first page of  
13 that document.  
14 A. Okay.  
15 (Witness reviewing document.)  
16 Q. Do you recognize that document?  
17 A. No, not exactly.  
18 Q. Okay. On the first page, the e-mail  
19 from you to Ms. Harper, October of 2013, any  
20 reason to doubt that you sent this e-mail?  
21 A. No.  
22 Q. Okay. Under "Suspicious Order  
23 Monitoring" in the middle of the page, do you  
24 see that?

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1 A. Yes.

2 Q. "Description. Support Legal

3 Department Regulatory Compliance in the arena of

4 interaction with the Drug Enforcement

5 Administration by managing and coordinating

6 enhancements with the SOM program."

7 Do you see that?

8 A. Yes.

9 Q. Do you recall the enhancements to the

10 SOM program that you managed or coordinated in

11 this time frame?

12 A. No, we were always constantly trying

13 to change it, make it better, so I don't

14 remember what in specific.

15 Q. Okay. The next paragraph says "Ensure

16 all orders placed on SOM hold are reviewed

17 thoroughly and accurately to ensure SOM DEA

18 Compliance."

19 In this time frame in 2013, who was

20 involved in the review of orders that were

21 placed on SOM hold?

22 A. Jen Buist, but I don't know when she

23 came on board.

24 Q. And what department did she work in?

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1 A. She was under government compliance at

2 that time.

3 Q. So was she the person who would review

4 an order that was placed on hold to determine

5 whether the order would be released?

6 A. Yes.

7 Q. And so in terms of your ensuring that

8 orders were thoroughly and accurately reviewed,

9 did you interact with her?

10 A. She -- if she was unsure of an order

11 and wanted to know some supporting data, she

12 would reach out to me. But I was the backup at

13 this time. So it's referring to any order that

14 I reviewed.

15 Q. Okay. But she had the ability to

16 review and release an order without consulting

17 with you, is that correct?

18 A. Yes.

19 Q. The next paragraph under "Employee

20 Evaluation" says "Fiscal year '13 has been a

21 challenging year for the Hobart site from the

22 Controlled Substances Compliance aspect."

23 What can you recall that made fiscal

24 year '13 a challenging year as you state in that

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1 sentence?

2 A. We had a very intensive DEA inspection

3 that year.

4 Q. Okay. And what aspects of the

5 inspection were particularly intensive, as you

6 can recall?

7 A. Just there was many investigators

8 there for six weeks.

9 Q. Did that investigation extend to any

10 aspects of the SOM program?

11 A. Yes.

12 Q. In what regard can you recall them

13 interacting with you with respect to SOM?

14 A. They were asking us about our SOM

15 program in which we, as did any other audit,

16 would explain the program at that time.

17 Q. Do you recall if DEA identified to you

18 any shortcomings or criticisms of the SOM

19 program?

20 A. Not that I remember.

21 (Whereupon, Mallinckrodt-Spaulding-5

22 was marked for identification.)

23 BY MR. GOTTO:

24 Q. We've marked as Exhibit 5 a two-page

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1 document beginning at Bates MNK-T1\_0000274080,

2 an e-mail dated -- well, series of e-mails dated

3 May of 2008. Would you take a moment to look at

4 those e-mails, please?

5 (Witness reviewing document.)

6 Q. Do you recognize those e-mails?

7 A. No.

8 Q. Okay. The May 12th e-mail from

9 Ms. Harper indicates that she's gathered a group

10 consisting of a few persons that she identifies

11 to review the suspicious order monitoring

12 program with the goal of making it more robust

13 in light of DEA activity, and she asks if you

14 would be willing to review a draft procedure and

15 serve on the team as a Hobart advisor.

16 Do you see that?

17 A. Yes.

18 Q. And do you recall her making that

19 request to you in 2008?

20 A. Based on -- only based on this e-mail.

21 I don't recall it.

22 Q. All right. And then you respond

23 "Absolutely - currently at DEA conference,"

24 correct?



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<p>1 A. Yes.</p> <p>2 Q. And no reason to doubt that you sent</p> <p>3 that e-mail, correct?</p> <p>4 A. No.</p> <p>5 Q. Okay. In Ms. Harper's e-mail under</p> <p>6 the dashed lines there are -- as an aside, she</p> <p>7 mentions in a conference she attended "among the</p> <p>8 agenda items was Suspicious Order Monitoring."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And "Other suggestions included," she</p> <p>12 states, "On-site visits for all controlled</p> <p>13 substance customers; Close scrutiny of small,</p> <p>14 independent pharmacies; Close scrutiny of pain</p> <p>15 management clinics."</p> <p>16 Are any of those three steps anything</p> <p>17 that you can recall being implemented at</p> <p>18 Mallinckrodt in this time frame in 2008?</p> <p>19 A. In 2008, no.</p> <p>20 Q. Do you recall when any of those steps</p> <p>21 were implemented at Mallinckrodt?</p> <p>22 A. We started on-site visits of</p> <p>23 controlled substance customers in 2010, '11 with</p> <p>24 the KeySource, Masters, and Cedardale that we</p>	<p>1 that the SOM program that was in place at</p> <p>2 Mallinckrodt complied with DEA requirements?</p> <p>3 A. Based on the knowledge we had at that</p> <p>4 time, yes.</p> <p>5 Q. Did there come a time when you had an</p> <p>6 understanding that the SOM program in place at</p> <p>7 Mallinckrodt did not comply with DEA</p> <p>8 requirements?</p> <p>9 A. No.</p> <p>10 (Whereupon, Mallinckrodt-Spaulding-6</p> <p>11 was marked for identification.)</p> <p>12 BY MR. GOTTO:</p> <p>13 Q. Exhibit 6 is a lengthy document</p> <p>14 beginning at Bates MNK-T1_0005187729. It's an</p> <p>15 e-mail attaching a PowerPoint presentation, the</p> <p>16 first page of which contains your name.</p> <p>17 It's a lengthy document, I can direct</p> <p>18 you to a few pages that I have some questions</p> <p>19 for you on rather than have you review the</p> <p>20 entire document. But certainly feel free to</p> <p>21 look at any part of it that you need to to</p> <p>22 answer any of my questions.</p> <p>23 Do you recall what the purpose of this</p> <p>24 document was?</p>
Page 139	Page 141
<p>1 spoke of.</p> <p>2 Q. Okay. In Ms. Harper's e-mail to you,</p> <p>3 she identifies a goal of making the SOM program</p> <p>4 more robust. Do you recall what the SOM program</p> <p>5 consisted of in May of 2008?</p> <p>6 A. Not exactly, no.</p> <p>7 Q. Do you have a general recollection?</p> <p>8 A. Generally it was just the algorithm.</p> <p>9 Q. And do you recall what the components</p> <p>10 of the algorithm were at this point?</p> <p>11 A. Only one of them. That was based on</p> <p>12 their previous order history.</p> <p>13 Q. Would that be the sort of threshold</p> <p>14 metric that you understood the DEA said was</p> <p>15 inadequate?</p> <p>16 MR. O'CONNOR: Objection to form.</p> <p>17 A. No. So a threshold is when you say,</p> <p>18 okay, they can only order up to 5,000 dosage</p> <p>19 units a month. This was based on what they</p> <p>20 historically had been ordering to know that --</p> <p>21 whether they were continuing to order in</p> <p>22 historical patterns.</p> <p>23 BY MR. GOTTO:</p> <p>24 Q. So was it your understanding in 2008</p>	<p>1 A. Yes.</p> <p>2 Q. What was it?</p> <p>3 A. It's what we used for training new</p> <p>4 employees when they started.</p> <p>5 Q. Okay. And just for the record, the</p> <p>6 cover e-mail is dated January of 2011, correct?</p> <p>7 A. Yes.</p> <p>8 Q. And did you prepare the portion of the</p> <p>9 presentation that's the slides that are behind</p> <p>10 your name?</p> <p>11 A. It was a combination of Karen Harper</p> <p>12 and myself.</p> <p>13 Q. Okay. If you turn to the page --</p> <p>14 unfortunately these are not numbered. Let me</p> <p>15 just count pages for you, 1, 2, 3, 4, 5, 6, 7,</p> <p>16 the eighth page in, there's "Statistics on</p> <p>17 National Drug Abuse Trends."</p> <p>18 Do you see that?</p> <p>19 A. "DEA Regulatory Authority" up on the</p> <p>20 top?</p> <p>21 Q. Well, it's immediately behind the</p> <p>22 slide that says "Security &amp; Controlled Substance</p> <p>23 Compliance."</p> <p>24 A. Oh, yes. Okay.</p>



<p style="text-align: right;">Page 142</p> <p>1 Q. So there's "Statistics on National  2 Drug Abuse Trends," and the following slide is  3 "Abuse Trends." Why was it important to give  4 this information to new hires in their training?  5 A. Because we wanted them to understand  6 why we have these security policies and  7 procedures around our processes, and why two  8 people have to be present at all times.  9 Q. Okay. And so the page -- the slide, I  10 think, the next one after the one you're on,  11 there you go, "Abuse Trends," identifies certain  12 statistical items such as "estimated 48 million  13 people have used prescription drugs for  14 non-medical reasons in their lifetimes." These  15 abuse trends were something that Mallinckrodt  16 tracked at the time, correct?  17 A. No. This is information that we  18 gleaned off of either DEA's website or NIDDA's  19 website.  20 Q. Okay. The following slide, "DEA  21 reiterates responsibilities." Do you see that  22 one?  23 A. Yes.  24 Q. And on this slide you make reference</p>	<p style="text-align: right;">Page 144</p> <p>1 against a registrant and their registration  2 regardless of who you are.  3 Q. All right. You can put that aside.  4 (Whereupon, Mallinckrodt-Spaulling-7  5 was marked for identification.)  6 BY MR. GOTTO:  7 Q. We've marked as Exhibit 7 a multi-page  8 document beginning at Bates MNK-T1_0000448773.  9 It's entitled "oxycodone Extended Release Risk  10 Map Action Plan." Let's take a look at that  11 document, and tell me if you recognize it.  12 A. No.  13 Q. You don't recall ever seeing this  14 before?  15 A. No, I don't remember it.  16 Q. Are you familiar with the -- with  17 Mallinckrodt having a risk map action plan with  18 respect to various products?  19 A. I'm aware that some products require  20 risk map programs.  21 Q. Okay. And do you know which products  22 require those programs?  23 A. Oxycodone ER was one of them. There's  24 several others, but I don't know them</p>
<p style="text-align: right;">Page 143</p> <p>1 to certain statements made by DEA in  2 correspondence to Mallinckrodt, correct?  3 A. Yes.  4 Q. Are these items of correspondence  5 the -- two of the items you referred to earlier  6 today in your testimony, letters from DEA?  7 A. The one letter is. I don't recall the  8 one that was specific for Mark Coverly.  9 Q. Okay. The one on the right from  10 Mr. Rannazzisi?  11 A. Yes.  12 Q. The following slide "Recent DEA  13 Actions Involving Distributors" which talks  14 about actions involving AmerisourceBergen,  15 Cardinal, and McKesson, why was it important to  16 provide that information to new hires?  17 A. Because we wanted them to understand  18 the importance of having a DEA license.  19 Q. And then the following several slides  20 involve specific examples, Masters  21 Pharmaceutical, Rite Aid Issues, CVS Fines. Why  22 was it important to provide that information to  23 new hires?  24 A. To show them that DEA can take action</p>	<p style="text-align: right;">Page 145</p> <p>1 specifically.  2 Q. And do you know why oxycodone requires  3 a risk map action plan?  4 A. No, that's an FDA requirement.  5 Q. Do you know if Mallinckrodt had any  6 other -- Mallinckrodt manufactured any other  7 opioid other than oxycodone that required a risk  8 map action plan?  9 A. Yes, there were others, but I don't  10 remember specifically which products.  11 Q. Did you have any involvement in the  12 preparation of the Oxycodone ER risk map action  13 plan?  14 A. I don't remember it, so I'm not sure.  15 Q. Okay. If you turn to Page 3 of the  16 document ending in Bates 775, under "Supply  17 Chain &amp; Security," you see your name appears on  18 several of the entries.  19 Do you see that?  20 A. Yes.  21 Q. So one entry, "Provide notification to  22 DEA of any confirmed diversion," and you're one  23 of the persons responsible there, correct?  24 A. Yes.</p>

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1 Q. Do you ever recall that occurring,  
2 that you provided notification to DEA of any  
3 confirmed diversion?  
4 A. No, that would have been a 106 form.  
5 Q. And do you recall ever providing a 106  
6 form to DEA confirming diversion on oxycodone?  
7 A. Oxycodone, or Oxycodone ER?  
8 Q. Oxycodone ER, I'm sorry.  
9 A. No, not without looking at my records.  
10 Q. Next item is "Notify Covidien  
11 management...of suspected diversion."  
12 Do you see that?  
13 A. Yes.  
14 Q. Do you recall ever doing that  
15 notification of Covidien management of suspected  
16 diversion of Oxycodone ER?  
17 A. No, I don't remember.  
18 Q. On the next page, Page 4, the -- one,  
19 two, three -- fourth item down, "Photographs of  
20 drivers authorized to handle controlled  
21 substances are maintained on file at the  
22 distribution center." Is that something that  
23 was done at Hobart?  
24 A. Yes.

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1 Q. Three items down from there, "Audit  
2 carrier records annually." Your name is listed.  
3 Is that something that you participated in?  
4 A. At that time, yes.  
5 Q. Do you recall an individual named John  
6 Gillies?  
7 A. Yes.  
8 Q. What was his role?  
9 A. He was not here at the time. This  
10 was -- Bill Ratliff was the security director.  
11 John Gillies is the vice president of global  
12 security.  
13 Q. Currently?  
14 A. Yes. John Gillies was Bill Ratliff's  
15 successor.  
16 Q. Okay. So to the extent Mr. Ratliff is  
17 identified as having responsibilities on this  
18 risk map action plan, currently those would be  
19 Mr. Gillies responsibilities?  
20 MR. O'CONNOR: Objection to form.  
21 BY MR. GOTTO:  
22 Q. As far as you know.  
23 A. Yes. We don't have this product  
24 anymore.

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1 Q. Okay. Do you interact with  
2 Mr. Gillies?  
3 A. Yes.  
4 Q. In what capacities?  
5 A. I escalate to him any law enforcement  
6 inquiries for either law information or the  
7 placebos as we talked about earlier, and if he  
8 contacts me for information, I provide it.  
9 Q. Have you ever had any -- has  
10 Mr. Gillies ever expressed any dissatisfaction  
11 with your work product?  
12 A. Not that I can recall.  
13 Q. Have you had any difficulties in  
14 interacting with Mr. Gillies over the years?  
15 A. No.  
16 MR. GOTTO: Let's go off the record.  
17 THE VIDEOGRAPHER: The time is  
18 12:32 p.m., and we're off the record.  
19 (Whereupon, a luncheon recess was  
20 taken.)  
21  
22  
23  
24

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1 AFTERNOON SESSION  
2  
3 THE VIDEOGRAPHER: The time is  
4 1:15 p.m., and we're on the record.  
5 BY MR. GOTTO:  
6 Q. Welcome back, Ms. Spaulding.  
7 A. Thank you.  
8 Q. Before our lunch break you had  
9 testified about the one suspicious order you  
10 could recall, which I think was a fentanyl order  
11 that went to a vet clinic, is that correct?  
12 A. Yes.  
13 Q. Okay. You'd agree with me that if a  
14 vet clinic purchased opioids and then resold  
15 them to a human pain clinic or a human  
16 physician, that would be a potentially  
17 suspicious order, wouldn't it?  
18 MR. O'CONNOR: Objection to form.  
19 A. I wouldn't know if a vet clinic sold  
20 it to anybody else. We would only have the  
21 direct sales. And a vet clinic wouldn't apply  
22 with chargebacks.  
23 BY MR. GOTTO:  
24 Q. So you're not aware of any situations

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1 in which Mallinckrodt opioids were purchased by  
2 a veterinary supply company and then resold to  
3 medical clinics or dispensing physicians?  
4 A. Not that I'm aware of.  
5 Q. And do you know if Mallinckrodt's  
6 records would include that information if it  
7 had, in fact, occurred?  
8 A. I don't know what our records -- that  
9 our records would include that.  
10 Q. In any event, you've never heard of  
11 that happening?  
12 A. Correct.  
13 (Whereupon, Mallinckrodt-Spaulding-8  
14 was marked for identification.)  
15 BY MR. GOTTO:  
16 Q. Just one last question on that one  
17 before you turn to that document.  
18 If you were aware of that happening,  
19 that a veterinary supply company purchasing from  
20 Mallinckrodt had resold to a medical clinic or  
21 dispensing physician, would you have  
22 investigated that as a potentially suspicious  
23 order?  
24 A. Yes, we would have raised that to the

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1 suspicious order monitoring team for evaluation.  
2 Q. Okay. I've just handed you what we've  
3 marked as Exhibit 8, which is a single-page  
4 document bearing Bates MNK-T1\_0006443249, an  
5 e-mail thread from 2005. Take a look at that  
6 for a moment, if you would, and tell me if you  
7 recognize it.  
8 A. Okay.  
9 Q. Do you recall those e-mails?  
10 A. No.  
11 Q. Okay. Do you know who Mike Spears  
12 was?  
13 A. Yes.  
14 Q. Who was he?  
15 A. Director of what we call PPT, product  
16 process technology.  
17 Q. And how about Laura Ashline?  
18 A. She's a project manager.  
19 Q. Okay. And Jim Walter?  
20 A. He was the site director.  
21 Q. Okay. Your e-mail to Mr. Spears and  
22 Ms. Ashline says "At the request of the DEA they  
23 would like to know the timeline for release of  
24 Oxycodone ER products (all strengths) into the

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1 marketplace as MS Contin is extremely abused and  
2 they want to know when we are going to start  
3 producing from this facility."  
4 Do you recall DEA making that inquiry  
5 of you?  
6 A. No.  
7 Q. Okay. Do you recall being aware in  
8 2005 that MS Contin was extremely abused?  
9 A. Only based on this e-mail.  
10 Q. Do you recall being aware in 2005 that  
11 Oxycodone ER would also have the potential to be  
12 abused?  
13 A. Only based on this e-mail.  
14 Q. And Mallinckrodt began manufacturing  
15 Oxycodone IR shortly after this, isn't that  
16 correct?  
17 A. We were manufacturing -- which  
18 strength of IR?  
19 Q. Well, in any strength.  
20 A. So we had been manufacturing oxycodone  
21 5-milligram prior to this. I don't remember  
22 when we started manufacturing oxycodone  
23 15-milligram or 30-milligram IR.  
24 Q. Okay. And Oxycodone IR also has the

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1 potential for abuse, correct?  
2 A. Yes.  
3 Q. And were you aware of that back in  
4 2005?  
5 A. I don't remember when I was aware of  
6 it.  
7 Q. Okay. All right. You can set that  
8 aside.  
9 (Whereupon, Mallinckrodt-Spaulding-9  
10 was marked for identification.)  
11 BY MR. GOTTO:  
12 Q. We've marked as Exhibit 9 a two-page  
13 e-mail thread beginning at Bates  
14 MNK-T1\_0000492214. Take a look at those  
15 e-mails, if you would, and tell me if you  
16 recognize them.  
17 (Witness reviewing document.)  
18 A. Yes.  
19 Q. And do you recognize these as e-mails  
20 from April of 2007 involving you and Ms. Harper  
21 as well as some others concerning a suspension  
22 of AmerisourceBergen by FDA -- by DEA?  
23 A. Yes.  
24 Q. Do you recall that circumstance

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1 occurring?  
2 A. Yes.  
3 Q. And AmerisourceBergen was a large  
4 customer of Mallinckrodt, correct?  
5 A. Yes.  
6 Q. And they, according to this press  
7 report, they were temporarily suspended as a  
8 result of shipping to certain pharmacies in  
9 Florida, correct?  
10 A. Based on this release, yes.  
11 Q. And this is dated in 2007. Were there  
12 any steps taken in 2007 in light of this  
13 suspension of AmerisourceBergen to evaluate  
14 whether any AmerisourceBergen orders from  
15 Mallinckrodt were suspicious?  
16 A. I don't remember if there was any  
17 specific steps.  
18 Q. Was there an audit conducted of  
19 AmerisourceBergen?  
20 MR. O'CONNOR: Objection to form.  
21 A. Not that I was directly involved in.  
22 BY MR. GOTTO:  
23 Q. Were you aware of an audit being  
24 conducted of AmerisourceBergen at any time in

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1 the 2007 time frame?  
2 A. No, not that I can recall.  
3 Q. Or in 2008?  
4 A. No.  
5 Q. Or 2009?  
6 A. No.  
7 Q. Or 2010?  
8 A. No.  
9 Q. Now, in your e-mail, the second one on  
10 the first page of the exhibit, you note that  
11 AmerisourceBergen had already been reinstated by  
12 the DEA. How did you know that?  
13 A. I don't remember how I knew back at  
14 that time.  
15 Q. And Ms. Harper in her April 27th  
16 e-mail says "sometimes we are met with internal  
17 pushback and the attitude that we are 'such big  
18 players' that DEA would never suspend our  
19 license."  
20 Do you see that?  
21 A. Yes.  
22 Q. Do you recall Ms. Harper expressing  
23 that sentiment to you, that sometimes that that  
24 attitude was expressed at Mallinckrodt?

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1 A. Yes.  
2 Q. And did you ever hear anyone express  
3 that attitude?  
4 A. There was internal pushback both ways,  
5 so they would push back on us and we would push  
6 back as well.  
7 Q. And when you say "they" in that  
8 setting, who is the they?  
9 A. Management, stakeholders in the  
10 business.  
11 Q. And pushback on whom?  
12 A. The compliance team.  
13 Q. And what would the form of the  
14 pushback be?  
15 A. If we wanted to purchase physical --  
16 additional equipment for physical security to  
17 make us -- to enhance, but at all times it  
18 was -- we were always in compliance. It was  
19 always to make us better or to be able to look  
20 at things differently. At no time were we not  
21 compliant. If we were, we -- the business would  
22 have given us anything we needed to be  
23 compliant.  
24 Q. So one form of pushback that you're

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1 recalling is where you may have made a request  
2 for some sort of enhancement to security and  
3 that request was rejected?  
4 MR. O'CONNOR: Objection to form.  
5 A. Was challenged.  
6 BY MR. GOTTO:  
7 Q. Do you remember any specific request  
8 in that regard?  
9 A. Nothing specific.  
10 Q. So the attitude that Ms. Harper is  
11 referring to is one that "we are 'such big  
12 players' that DEA would never suspend our  
13 license." If you were in compliance with DEA  
14 regulation and you were requesting an  
15 enhancement, how would that trigger a response  
16 in the nature of "we are 'such big players' that  
17 DEA would never suspend our license"?  
18 MR. O'CONNOR: Objection to form.  
19 A. I don't know what example that Karen  
20 is referring to in this -- in her comment.  
21 BY MR. GOTTO:  
22 Q. You don't recall any discussions with  
23 her on that point in this time frame?  
24 A. No.

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1 Q. Did Ms. Harper ever express to you any  
2 frustration with the slow pace of enhancing the  
3 SOM program?  
4 MR. O'CONNOR: Objection to form.  
5 A. Not that I can recall.  
6 BY MR. GOTTO:  
7 Q. It took quite a while from when you  
8 began working on enhancing the program until  
9 there actually was an enhanced program in place,  
10 wasn't it?  
11 MR. O'CONNOR: Objection to form.  
12 A. I don't know what that time frame is.  
13 I don't know what a while is.  
14 BY MR. GOTTO:  
15 Q. More than three years?  
16 A. I don't know, because they were  
17 working on it from the corporate aspect.  
18 Q. In terms of when you were first aware  
19 of there being work on enhancing the SOM program  
20 until the time when the enhanced program was  
21 actually implemented, that was more than three  
22 years, wasn't it?  
23 MR. O'CONNOR: Objection to form.  
24 A. I don't remember. We were constantly

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1 working on it. There was always a program in  
2 place, we were just always tweaking it, making  
3 it better.  
4 BY MR. GOTTO:  
5 Q. Were you personally frustrated with  
6 the pace at which the enhancement of the SOM  
7 program was taking place?  
8 A. No, not that I can recall.  
9 Q. And you don't recall Ms. Harper  
10 expressing any frustration in that regard?  
11 A. No, not to me.  
12 (Whereupon, Mallinckrodt-Spaulding-10  
13 was marked for identification.)  
14 BY MR. GOTTO:  
15 Q. We've marked as Exhibit 10 a  
16 multi-page e-mail thread beginning at Bates  
17 MNK-T1\_0001792949. Please take a moment to look  
18 at those e-mails, and tell me if you recognize  
19 them.  
20 (Witness reviewing document.)  
21 Q. I just have questions for you on the  
22 first page.  
23 (Witness reviewing document.)  
24 A. Okay.

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1 Q. In your e-mail on June 24th, you  
2 indicate "Patti is sharing with her group as  
3 well."  
4 Who is Patti?  
5 A. Patti Woznick was the purchasing  
6 manager.  
7 Q. Okay. And what was her group?  
8 A. The purchasing department, and the  
9 ARCOS coordinator at the time was reporting to  
10 Patti.  
11 Q. Okay. And Ms. Harper was forwarding  
12 you some press reports regarding oxycodone and  
13 OxyContin, correct?  
14 A. Yes.  
15 Q. And what would be the reason for Patti  
16 sharing that information with her group?  
17 A. Because she had a member of compliance  
18 on her team.  
19 Q. Fair to say that by mid 2008 you were  
20 aware of the potential for diversion and abuse  
21 of oxycodone, correct?  
22 A. Yes. Yes.  
23 Q. And fair to say it was a matter of  
24 concern for Ms. Harper at that time?

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1 MR. O'CONNOR: Objection to form.  
2 A. I can't speculate on what Karen felt  
3 or knew.  
4 BY MR. GOTTO:  
5 Q. You don't recall her expressing to you  
6 at that time any concerns about the potential  
7 for diversion or abuse of oxycodone?  
8 MR. O'CONNOR: Objection to form.  
9 A. Not at this time.  
10 BY MR. GOTTO:  
11 Q. When can you recall her first  
12 expressing any such concerns to you?  
13 MR. O'CONNOR: Objection to form.  
14 A. I don't remember exact dates or  
15 timelines.  
16 BY MR. GOTTO:  
17 Q. You understood in 2008, didn't you,  
18 that as a DEA registrant Mallinckrodt had an  
19 obligation to design and implement a suspicious  
20 order monitoring program, correct?  
21 A. Yes.  
22 Q. And you understood that a purpose of  
23 that program was to function as an  
24 anti-diversion mechanism, correct?



<p style="text-align: right;">Page 162</p> <p>1 MR. O'CONNOR: Objection to form.</p> <p>2 A. I understood it to be a regulation in</p> <p>3 the CFR.</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. Did you understand one of the purposes</p> <p>6 for suspicious order monitoring to deter</p> <p>7 diversion?</p> <p>8 A. Yes.</p> <p>9 Q. And you understood in 2008 that as a</p> <p>10 DEA registrant Mallinckrodt also had the</p> <p>11 obligation to take steps to protect against</p> <p>12 diversion of the controlled substances that it</p> <p>13 manufactured?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. We had to maintain effective controls</p> <p>16 to detect diversion within the manufacturing</p> <p>17 site.</p> <p>18 BY MR. GOTTO:</p> <p>19 Q. Did you have an understanding as to</p> <p>20 whether Mallinckrodt had any duties with respect</p> <p>21 to controlling against diversion with respect to</p> <p>22 its products after they left the manufacturing</p> <p>23 site?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 164</p> <p>1 something that somebody else saw on the SOM team</p> <p>2 or it was broader.</p> <p>3 Q. Was the subject of conducting inquiry</p> <p>4 into your customers' customers something that</p> <p>5 was covered in any of the DEA-sponsored</p> <p>6 educational programs that you attended?</p> <p>7 A. I vaguely remember one of the DEA</p> <p>8 conferences talking about know your customer's</p> <p>9 customer, but I don't know when that was.</p> <p>10 Q. Do you recall if at that time</p> <p>11 Mallinckrodt was taking steps to know its</p> <p>12 customer's customer?</p> <p>13 A. No, because I don't remember what the</p> <p>14 correlation time was.</p> <p>15 Q. How about the Buzzeo conferences, do</p> <p>16 you recall that topic, knowing your customer's</p> <p>17 customer, being covered at any of those</p> <p>18 conferences?</p> <p>19 A. No.</p> <p>20 Q. Do you recall that in 2008 there was</p> <p>21 an initiative at Mallinckrodt to enhance the SOM</p> <p>22 program?</p> <p>23 A. Yes.</p> <p>24 Q. And do you recall what triggered that?</p>
<p style="text-align: right;">Page 163</p> <p>1 Q. Did you not have an understanding, or</p> <p>2 did you understand that it did not have any such</p> <p>3 obligation?</p> <p>4 A. So my understanding was that we had an</p> <p>5 obligation to maintain effective controls from</p> <p>6 us to the customer, to our direct customer.</p> <p>7 Back in 2008 we didn't know about downstream</p> <p>8 customers, or have the inclination that we</p> <p>9 needed to be looking at downstream customers.</p> <p>10 Q. Okay. And when you say "downstream</p> <p>11 customers," you mean your customers' customers,</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. And when did you first -- when can you</p> <p>15 recall first beginning to conduct any inquiry</p> <p>16 into Mallinckrodt's customers' customers?</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. That would have been when we started</p> <p>19 looking at chargebacks.</p> <p>20 BY MR. GOTTO:</p> <p>21 Q. And do you recall when that was?</p> <p>22 A. I don't.</p> <p>23 Q. Do you recall what triggered that?</p> <p>24 A. I don't. I don't know if it was</p>	<p style="text-align: right;">Page 165</p> <p>1 A. No.</p> <p>2 Q. How did you learn about that</p> <p>3 initiative?</p> <p>4 A. The initiative of --</p> <p>5 Q. Enhancing the SOM program.</p> <p>6 A. Through Karen Harper.</p> <p>7 Q. And was one of the reasons for that</p> <p>8 initiative increased DEA scrutiny with respect</p> <p>9 to Mallinckrodt's distributors?</p> <p>10 A. I don't know that firsthand.</p> <p>11 Q. Was one of the reasons any of the</p> <p>12 letters from Mr. Rannazzisi that you mentioned</p> <p>13 earlier today?</p> <p>14 A. It could be.</p> <p>15 Q. But you don't recall?</p> <p>16 A. I don't recall exactly, no.</p> <p>17 Q. Do you recall in 2008 being aware that</p> <p>18 diversion of prescription opioids was being</p> <p>19 identified publicly as a significant health</p> <p>20 issue?</p> <p>21 MR. O'CONNOR: Objection to form.</p> <p>22 A. I'm aware of it. I don't remember</p> <p>23 when I became aware of it.</p> <p>24 (Whereupon, Mallinckrodt-Spaulling-11</p>

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1 was marked for identification.)  
2 BY MR. GOTTO:  
3 Q. We've marked as Exhibit 11 a two-page  
4 DEA letter beginning at Bates MNK-T1\_0000270069.  
5 Take a look at that, and tell me if you  
6 recognize that as one of the letters from  
7 Mr. Rannazzisi that you testified about earlier  
8 today.  
9 A. Yes.  
10 Q. Do you recall seeing this letter in  
11 late 2007 or early 2008?  
12 A. I recall seeing it. I would assume it  
13 was when this letter was sent. I don't remember  
14 exactly.  
15 Q. And do you recall who provided it to  
16 you?  
17 A. So based on the stamp, this came into  
18 our regulatory affairs department, and they  
19 probably shared it with me.  
20 Q. Okay. Do you recall when you first  
21 saw this letter if this provided any information  
22 with respect to DEA regulation of which you were  
23 not aware until you read the letter?  
24 MR. O'CONNOR: Objection to form.

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1 A. I remember that the letter called out  
2 that they didn't want excessive order reports  
3 anymore. They only wanted orders that were  
4 suspicious.  
5 BY MR. GOTTO:  
6 Q. Okay. And excessive order reports  
7 were something that you had provided previously,  
8 correct?  
9 A. Yes.  
10 Q. And did you stop doing that after  
11 receiving this letter?  
12 A. I stopped doing it. I don't know that  
13 it was a result of receiving this letter or  
14 when.  
15 Q. The second paragraph of the letter in  
16 the second line notes that manufacturers and  
17 distributors must maintain effective controls  
18 against diversion.  
19 Do you see that?  
20 A. Yes.  
21 Q. You were aware of that before you  
22 received this letter, correct?  
23 A. Yes.  
24 Q. A little later in that paragraph,

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1 about halfway through there's a sentence that  
2 says "The regulation clearly indicates that it  
3 is the sole responsibility of the registrant to  
4 design and operate such a system."  
5 Do you see that in that system to  
6 disclose suspicious orders?  
7 A. Yes.  
8 Q. You were aware of that before you  
9 received the letter, correct?  
10 A. Yes.  
11 Q. In the following paragraph, the second  
12 sentence says "Filing a monthly report of  
13 completed transactions does not meet the  
14 regulatory requirement to report suspicious  
15 orders."  
16 Were you aware of that before you  
17 received this letter?  
18 MR. O'CONNOR: Objection to form.  
19 A. I'm not following where you are in the  
20 letter.  
21 BY MR. GOTTO:  
22 Q. I'm sorry. The third paragraph,  
23 second sentence, "Filing a monthly report."  
24 A. Okay.

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1 Q. Were you aware of what that sentence  
2 said before you received this letter?  
3 MR. O'CONNOR: Same objection.  
4 A. I don't remember.  
5 BY MR. GOTTO:  
6 Q. Two sentences later in that paragraph  
7 it says "Registrants must conduct an independent  
8 analysis of suspicious orders prior to  
9 completing a sale to determine whether the  
10 controlled substances are likely to be diverted  
11 from legitimate channels."  
12 Do you see that?  
13 A. Yes.  
14 Q. Were you aware of that before  
15 receiving this letter?  
16 A. I don't remember.  
17 Q. But in any event, you were aware of it  
18 after you read this letter, correct?  
19 A. Yes.  
20 Q. Was it your understanding in late  
21 2007, early 2008 that Mallinckrodt's procedures  
22 complied with that requirement, namely to  
23 conduct an independent analysis of suspicious  
24 orders before completing a sale to determine

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1 whether the controlled substances were likely to  
2 be diverted from legitimate channels?  
3 MR. O'CONNOR: Objection.  
4 A. Yes.  
5 BY MR. GOTTO:  
6 Q. What did that independent analysis  
7 consist of in this time frame?  
8 A. I don't remember exactly. It was  
9 being done at corporate.  
10 Q. It's not something you were involved  
11 in at this time?  
12 A. I don't think so. I don't remember.  
13 Q. Do you know who at corporate was  
14 involved in that?  
15 A. Customer service managers.  
16 Q. The next paragraph says "The  
17 regulation specifically states that suspicious  
18 orders include orders of an unusual size, orders  
19 deviating substantially from a normal pattern,  
20 and orders of unusual frequency."  
21 Do you see that?  
22 A. Yes.  
23 Q. Were you aware of that before you  
24 received this letter?

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1 A. Yes.  
2 Q. On the second page, the first  
3 paragraph on that page says "Registrants that  
4 rely on rigid formulas to" determine "whether an  
5 order is suspicious may be failing to detect  
6 suspicious orders."  
7 Do you see that?  
8 A. Yes.  
9 Q. Were you aware of that before  
10 receiving this letter?  
11 A. I don't remember.  
12 Q. The following sentence says "For  
13 example, a system that identifies orders as  
14 suspicious only if the total amount of the  
15 controlled substance ordered during one month  
16 exceeds the amount ordered the previous month by  
17 a certain percentage or more is insufficient."  
18 Do you see that?  
19 A. Yes.  
20 Q. Were you aware before receiving this  
21 letter that a system of the type described in  
22 that sentence is insufficient?  
23 A. I don't remember.  
24 Q. Do you know if at this time

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1 Mallinckrodt's SOM program -- well, do you know  
2 if at the time of this letter the description  
3 that I just read from this letter would apply to  
4 Mallinckrodt's SOM program as it was followed in  
5 this time frame?  
6 MR. O'CONNOR: Objection to form.  
7 A. I don't know what the algorithm in  
8 place was at the time of this letter.  
9 BY MR. GOTTO:  
10 Q. Okay. You can set that aside.  
11 (Whereupon, Mallinckrodt-Spaulding-12  
12 was marked for identification.)  
13 BY MR. GOTTO:  
14 Q. We've marked as Exhibit 11 a one-page  
15 document MNK-T1\_0000496062, Suspicious Order  
16 Monitoring Team Charter.  
17 MR. O'CONNOR: Counsel, I think it's  
18 12.  
19 MR. GOTTO: I'm sorry. Is it 12?  
20 MS. REYES: It is 12.  
21 MR. GOTTO: Sorry. I apologize.  
22 Exhibit 12.  
23 MR. O'CONNOR: No problem.  
24 BY MR. GOTTO:

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1 Q. Updated 4/7/11. Take a look at that  
2 document, if you would, tell me if you recognize  
3 it.  
4 (Witness reviewing document.)  
5 A. Okay.  
6 Q. Do you recognize that document?  
7 A. No, I don't remember it.  
8 Q. Appears to be a team charter for the  
9 SOM team. You're listed on -- as a member of  
10 the steering committee.  
11 Do you see that?  
12 A. Yes.  
13 Q. And is that consistent with your  
14 recollection that you were a member of the SOM  
15 steering committee at least as of April 7 of  
16 2011?  
17 A. Yes.  
18 Q. Do you recall when you became a member  
19 of the steering committee?  
20 A. No.  
21 Q. When you were a member, do you  
22 recall -- are you still a member of the steering  
23 committee?  
24 A. Yes.

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1 Q. And does the steering committee meet  
2 regularly?  
3 A. Yes.  
4 Q. How frequently?  
5 A. Monthly.  
6 Q. Has that been the case at least since  
7 April of 2011?  
8 A. Yes.  
9 Q. Does it maintain minutes of meetings?  
10 A. Not that I'm aware of.  
11 Q. Any other formal documentation of its  
12 actions or deliberations?  
13 A. No.  
14 (Whereupon, Mallinckrodt-Spaulding-13  
15 was marked for identification.)  
16 BY MR. GOTTO:  
17 Q. We've marked as Exhibit 13 a two-page  
18 document starting MNK-T1\_0007026341. Please  
19 take a look at those pages, and tell me if you  
20 recognize them.  
21 (Witness reviewing document.)  
22 A. Yes.  
23 Q. And what are they?  
24 A. So this is actually -- I know the

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1 header says suspicious orders, but these are  
2 what we call as peculiar or unusual orders, so  
3 they're hits to the algorithm.  
4 Q. Okay. Your cover e-mail, which is  
5 dated in April of 2014 to Ms. Harper, says "I  
6 can recall having a suspicious order monitoring  
7 system in place of some type with the start of  
8 distribution activities from Hobart 2001,  
9 however the attached is the earliest SOM report  
10 that I have in my e-mail system." And the  
11 attachment is from December of 2003, correct?  
12 A. Yes.  
13 Q. And this identifies four transactions.  
14 And I take it from your earlier answer these  
15 were identified as peculiar, correct?  
16 A. Yes.  
17 Q. And is it the case that none of these  
18 were ultimately determined to be suspicious?  
19 A. Correct.  
20 Q. And I think you've testified earlier  
21 the only order that you can recall being  
22 identified as suspicious was the fentanyl order  
23 to the vet clinic, correct?  
24 A. The only one I know of, yes.

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1 Q. Okay. Do you recall why you sent this  
2 report to Ms. Harper in 2014?  
3 A. She would have had to have requested  
4 it is the only reason I would have sent it.  
5 Q. Now, in your cover e-mail you mention  
6 a suspicious order monitoring of some type from  
7 2001. Was there a written suspicious order  
8 monitoring program in place before 2008?  
9 MR. O'CONNOR: Object to form.  
10 A. I don't know that it was written, that  
11 there was a written policy on it.  
12 BY MR. GOTTO:  
13 Q. Okay. So you don't recall seeing a  
14 written policy prior to 2008?  
15 A. No.  
16 Q. How did you come to know what the  
17 program was if it wasn't written?  
18 A. Because Elizabeth McPhail at the time  
19 would have trained me on what to look for in the  
20 orders.  
21 Q. And what do you recall her training  
22 you on in that regard?  
23 A. To look at the orders that come out,  
24 and if they were of concern to research them

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1 further.  
2 Q. And did she train you as to what  
3 characteristics of an order might raise concern?  
4 A. No, because we really didn't have a  
5 whole lot of information of what was unusual.  
6 Q. And so, for example, the orders  
7 identified as peculiar in the attachment to  
8 Exhibit 13, do you recall how you identified  
9 those orders as peculiar?  
10 A. So the system would have ran these  
11 orders against whatever algorithm was in place  
12 at that time, and then these orders, these  
13 orders went on hold. So the report is saying  
14 their previous year-to-date average is 643, and  
15 this order was for 1,380.  
16 Q. Okay. So these orders were identified  
17 by application of the algorithm that you  
18 understand was in place at the time?  
19 A. Yes.  
20 Q. But you don't know what the components  
21 of that algorithm were, correct?  
22 A. All I know, it was based on previous  
23 history. I don't know the specifics.  
24 Q. Okay. You can set that aside.

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1 (Whereupon, Mallinckrodt-Spaulding-14  
2 was marked for identification.)  
3 BY MR. GOTTO:  
4 Q. We've marked as Exhibit 14 a  
5 single-page document, MNK-T1\_0004282621. It's a  
6 2007 e-mail from you to Sarah Heideman.  
7 First of all, who was Sarah Heideman?  
8 A. I don't remember.  
9 Q. Okay.  
10 A. I don't know.  
11 Q. In the body of your e-mail -- first of  
12 all, no reason to doubt you sent this e-mail,  
13 correct?  
14 A. No.  
15 Q. The body of your e-mail, you say "DEA  
16 requires us to report any 'suspicious orders'.  
17 IS programmed a report that takes last year's  
18 average YTD and comes up with a formula and  
19 anything outside of that formula shows on this  
20 report."  
21 Is that the algorithm that you're  
22 referring to?  
23 A. Yes.  
24 Q. And you have -- you ask Ms. Heideman

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1 to take a look and let you know what she thinks.  
2 But you don't recall who Ms. Heideman  
3 was or why you sent her this e-mail?  
4 A. Based on the context of this e-mail,  
5 it leads me to believe Sarah Heideman was the  
6 project -- or the account manager for Walmart,  
7 because I'm asking her specifically about  
8 Walmart orders.  
9 Q. Okay. And you note in your e-mail,  
10 "It appears to me that Walmart is ordering  
11 double what was last years' YTD amount, more  
12 than the 20 percent market share increase."  
13 Your reference there to market share,  
14 what are you referring to?  
15 A. So we would have received information  
16 from the marketing group as to which customers  
17 have -- which have how much of the market share.  
18 So at this time I must have been advised by  
19 somebody in marketing that Walmart had  
20 20 percent market share.  
21 Q. Or 20 percent market share increase?  
22 A. Yeah. Yes.  
23 Q. Okay. So you're comparing that  
24 increase to the increase in the size of their

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1 order, is that what you're saying in this  
2 sentence?  
3 A. YTD is year-to-date, so the formula at  
4 that time was taking the last year's  
5 year-to-date average, and this order was double  
6 their last year year-to-date average.  
7 Q. And so would this -- is this e-mail an  
8 example of your looking at an order that had  
9 been identified as peculiar to determine whether  
10 it was suspicious?  
11 A. At this time, yes.  
12 Q. And you did that by providing this  
13 information to Ms. Heideman and asking her for  
14 some feedback on it?  
15 A. Yes.  
16 Q. And do you recall if you ultimately  
17 concluded whether this order was suspicious or  
18 not?  
19 A. It wasn't reported to DEA, that I'm  
20 aware of.  
21 Q. Okay.  
22 (Whereupon, Mallinckrodt-Spaulding-15  
23 was marked for identification.)  
24 BY MR. GOTTO:

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1 Q. We've marked as Exhibit 15 a two-page  
2 document beginning at MNK-T1\_0000274399, an  
3 e-mail exchange involving you and Ms. Harper,  
4 "Re: Controlled Substance Suspicious Order  
5 Monitoring Team Update." Take a look at those  
6 e-mails, and tell me if you recognize them.  
7 (Witness reviewing document.)  
8 A. Okay.  
9 Q. Okay. Do you recognize those e-mails?  
10 A. No, I don't remember them  
11 specifically.  
12 Q. Okay. The second e-mail on the page  
13 from you to Ms. Harper dated June 17, do you see  
14 that?  
15 A. Yes.  
16 Q. Any reason to doubt you sent that  
17 e-mail?  
18 A. No.  
19 Q. Okay. You say to Ms. Harper, the  
20 first paragraph suggests on the customer  
21 checklist, "fill in what type of DEA  
22 registration so that we may be able to identify  
23 if a customer is ordering a suspicious amount  
24 against a specific registration type."



<p style="text-align: right;">Page 182</p> <p>1 What did you mean by that?</p> <p>2 A. So if a customer that's listed as a</p> <p>3 researcher is ordering a huge amount of product,</p> <p>4 that would not be normal for a researcher</p> <p>5 license.</p> <p>6 Q. Okay. And the customer checklist that</p> <p>7 you're referring to here, what was that?</p> <p>8 A. To the best that I recall, there</p> <p>9 was -- the SOM corporate team was developing</p> <p>10 checklists to be sent out to our customers.</p> <p>11 Q. Was this part of the enhancement of</p> <p>12 the SOM?</p> <p>13 A. Yes.</p> <p>14 Q. The last paragraph of your June 17th,</p> <p>15 or the last substantive paragraph says "With the</p> <p>16 new procedures, what kind of report will I send</p> <p>17 to the DEA? I realize that we will DEA report</p> <p>18 any order that is deemed suspicious by yours and</p> <p>19 Bill's group, but what if we go a quarter</p> <p>20 without a suspicious order?"</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. So was your -- does that indicate that</p> <p>24 up until this time there was a regular quarterly</p>	<p style="text-align: right;">Page 184</p> <p>1 A. I don't know what he provided.</p> <p>2 (Whereupon, Mallinckrodt-Spaulding-16</p> <p>3 was marked for identification.)</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. We've marked as Exhibit 16 a two-page</p> <p>6 document beginning at Bates MNK-T1_0002940798.</p> <p>7 Please take a look at those and tell me if you</p> <p>8 can identify them.</p> <p>9 (Witness reviewing documents.)</p> <p>10 A. Okay.</p> <p>11 Q. Do you recognize those documents?</p> <p>12 A. Yes.</p> <p>13 Q. What are they?</p> <p>14 A. These were the quarterly reports that</p> <p>15 I was combining and sending to DEA.</p> <p>16 Q. Okay. And these were -- what is</p> <p>17 reported on the report?</p> <p>18 A. I'm not sure I understand your</p> <p>19 question.</p> <p>20 Q. I'm sorry. How does some -- how does</p> <p>21 an order -- what is it about an order that</p> <p>22 causes you to include it on this report?</p> <p>23 A. So if it hits the criteria for the</p> <p>24 algorithm.</p>
<p style="text-align: right;">Page 183</p> <p>1 report you were sending to the DEA?</p> <p>2 A. It was the excessive orders report.</p> <p>3 Q. Okay. And so does that paragraph</p> <p>4 indicate that you were not going to be providing</p> <p>5 that report to the DEA anymore? Correct?</p> <p>6 A. Correct.</p> <p>7 Q. And so what was the answer to the</p> <p>8 question that you posed in that paragraph?</p> <p>9 A. I don't remember.</p> <p>10 Q. You can set that aside.</p> <p>11 Do you know who Bill Rausch was?</p> <p>12 A. Bill Rausch --</p> <p>13 Q. Rausch.</p> <p>14 A. -- or Jim Rausch?</p> <p>15 Q. Jim Rausch, I'm sorry.</p> <p>16 A. Jim Rausch, yes.</p> <p>17 Q. Who was he?</p> <p>18 A. He was a customer service manager.</p> <p>19 Q. Did he have any involvement at any</p> <p>20 time that you can recall in the SOM process?</p> <p>21 A. Yes, he was the customer service</p> <p>22 manager reviewing the peculiar order report.</p> <p>23 Q. Okay. And did he provide reports to</p> <p>24 the DEA from time to time that you know of?</p>	<p style="text-align: right;">Page 185</p> <p>1 Q. Okay. So these would be, again,</p> <p>2 peculiar orders under the Mallinckrodt</p> <p>3 terminology?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And so did you report all</p> <p>6 peculiar orders on a quarterly basis to the DEA</p> <p>7 for some period of time?</p> <p>8 A. We reported all orders that -- these</p> <p>9 are all clinic orders.</p> <p>10 Q. Clinic orders that had been identified</p> <p>11 as peculiar?</p> <p>12 A. Yes.</p> <p>13 Q. As compared to what other types of</p> <p>14 orders?</p> <p>15 A. So the distributors have been removed.</p> <p>16 Q. Okay. And what was the reason for</p> <p>17 that?</p> <p>18 A. I don't remember specifically. I</p> <p>19 remember being told not to include the</p> <p>20 distributors into the report, but I don't</p> <p>21 remember who told me not to include the</p> <p>22 distributors.</p> <p>23 Q. Would it have been someone other than</p> <p>24 Ms. Harper?</p>

<p style="text-align: right;">Page 186</p> <p>1 A. It could have been.</p> <p>2 Q. Okay. And you don't remember -- you</p> <p>3 weren't given a reason for that, I take it?</p> <p>4 A. I know that I was told not to include</p> <p>5 them, but I can't remember by whom. It could</p> <p>6 have been any number of people.</p> <p>7 Q. So in Exhibit 15, that was an e-mail</p> <p>8 in 2008 in which you posed the question about</p> <p>9 what kind of report will you be sending to the</p> <p>10 DEA going forward.</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. In 2010, judging from Exhibit 16, in</p> <p>14 2010 you were still providing some sort of</p> <p>15 quarterly report to the DEA, correct?</p> <p>16 A. Yes. Well, this was -- the last</p> <p>17 report was 2008. My e-mail to Karen was 2010,</p> <p>18 but the last report was 2008.</p> <p>19 Q. Okay. So your 2010 e-mail is</p> <p>20 attaching a 2008 report?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. So the attachment to Exhibit 16</p> <p>23 is the final report that you sent to the DEA,</p> <p>24 the final quarterly report?</p>	<p style="text-align: right;">Page 188</p> <p>1 A. Roughly, yes.</p> <p>2 Q. Okay. And do you continue -- is that</p> <p>3 procedure still in place?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. So from the attachment to</p> <p>6 Exhibit 16, after that report and prior to the</p> <p>7 time when you in 2012 began the twice daily</p> <p>8 unusual order report to the DEA, was there any</p> <p>9 other reporting to the DEA other than if a</p> <p>10 report was -- if an order was determined to be</p> <p>11 suspicious?</p> <p>12 A. Not by me, but I don't know if DEA --</p> <p>13 or if corporate was sending anything to DEA.</p> <p>14 Q. Okay. But as far as reports that</p> <p>15 you're aware of, you're not aware of any during</p> <p>16 that time period?</p> <p>17 A. Correct. 2008 was the last of the</p> <p>18 quarterly excessive order reports. In 2012</p> <p>19 started the peculiar order reports.</p> <p>20 Q. Okay. You can set that aside.</p> <p>21 (Whereupon, Mallinckrodt-Spaulling-17</p> <p>22 was marked for identification.)</p> <p>23 BY MR. GOTTO:</p> <p>24 Q. We've marked as Exhibit 17 a</p>
<p style="text-align: right;">Page 187</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And so after the report that's</p> <p>3 attached to Exhibit 16, what, if any, report did</p> <p>4 you provide to the DEA with respect to orders</p> <p>5 that were identified as peculiar but were not</p> <p>6 identified as suspicious?</p> <p>7 A. So what reports did we make to the DEA</p> <p>8 that were peculiar but not suspicious?</p> <p>9 Q. Yes.</p> <p>10 A. In what time frame?</p> <p>11 Q. Well, after the report that is</p> <p>12 attached to Exhibit 16.</p> <p>13 A. Right. We stopped this because this</p> <p>14 was basically the excessive order report, and</p> <p>15 the letter came out that said they didn't want</p> <p>16 the excessive order report, so that's why we</p> <p>17 discontinued sending them to DEA. And then we</p> <p>18 would have only reported suspicious orders.</p> <p>19 Q. Okay.</p> <p>20 A. In 2012, one of the iterations in the</p> <p>21 enhancements involved sending the peculiar order</p> <p>22 report, at this time we called it unusual order</p> <p>23 report, to DEA twice daily.</p> <p>24 Q. And that was in 2012?</p>	<p style="text-align: right;">Page 189</p> <p>1 multi-page e-mail thread, MNK-T1_0005663239 is</p> <p>2 the beginning. Take a moment to look at those.</p> <p>3 My questions are principally about</p> <p>4 your March 5, 2012 e-mail that begins the</p> <p>5 thread.</p> <p>6 (Witness reviewing document.)</p> <p>7 A. Okay.</p> <p>8 Q. Do you recognize those e-mails?</p> <p>9 A. I'm sorry?</p> <p>10 Q. Do you recognize those e-mails?</p> <p>11 A. No.</p> <p>12 Q. Okay. Turning to your March 5, 2012</p> <p>13 e-mail, which is on the third page, any reason</p> <p>14 to doubt you sent that e-mail?</p> <p>15 A. No.</p> <p>16 Q. Okay. So this is an e-mail that you</p> <p>17 send to a number of persons regarding an order</p> <p>18 from Quest Pharmaceuticals, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you indicate "I am unsure of the</p> <p>21 Product Manager for Hydrocodone and the NAM for</p> <p>22 Quest," correct?</p> <p>23 A. Yes.</p> <p>24 Q. And that's the reason you sent it to</p>

<p style="text-align: right;">Page 190</p> <p>1 all those parties, right?</p> <p>2 A. Correct.</p> <p>3 Q. Okay. Was there a -- well, strike</p> <p>4 that.</p> <p>5 So the order from Quest had been</p> <p>6 identified as a peculiar order, is that fair?</p> <p>7 A. Unusual, yes.</p> <p>8 Q. Peculiar or unusual?</p> <p>9 A. Yeah.</p> <p>10 Q. Meaning that it triggered the --</p> <p>11 whatever the algorithm was in place at the time,</p> <p>12 this triggered it?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And you indicate that the</p> <p>15 "items are double and in some cases triple the</p> <p>16 quantity previously ordered." Would your</p> <p>17 procedure at this time in 2012 have been to</p> <p>18 inquire of the product manager or the NAM to get</p> <p>19 further information with respect to an order</p> <p>20 that triggered the algorithm?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. And here you weren't sure who</p> <p>23 those individuals were, correct?</p> <p>24 A. Correct.</p>	<p style="text-align: right;">Page 192</p> <p>1 information.</p> <p>2 Q. Did you ever make inquiry of the</p> <p>3 customer service department to gain further</p> <p>4 information with respect to orders that had been</p> <p>5 identified as peculiar?</p> <p>6 A. Yes.</p> <p>7 Q. And who did you make inquiry of in the</p> <p>8 customer service department?</p> <p>9 A. It depends on the customer service rep</p> <p>10 assigned to the account.</p> <p>11 Q. Okay. So in this example on March 5th</p> <p>12 of 2012, are you making inquiry here of customer</p> <p>13 service?</p> <p>14 A. No.</p> <p>15 Q. And why not?</p> <p>16 A. Because customer service may not know</p> <p>17 why their order is higher. The product manager</p> <p>18 or the account manager may. I would inquire to</p> <p>19 customer service if I suspected that an order</p> <p>20 had been duplicated. There might have been an</p> <p>21 order entry error. But in this case, because of</p> <p>22 the order quantities, I went to the account</p> <p>23 manager who would know what the customer was</p> <p>24 ordering.</p>
<p style="text-align: right;">Page 191</p> <p>1 Q. Did you have any program in place to</p> <p>2 be made aware of who the project manager --</p> <p>3 product manager and NAMs were for particular</p> <p>4 products or customers?</p> <p>5 A. No.</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. Because they could change. So NAM is</p> <p>8 national account manager, and the product</p> <p>9 manager.</p> <p>10 BY MR. GOTTO:</p> <p>11 Q. Okay. And so when you had a peculiar</p> <p>12 or unusual order, was it your practice to</p> <p>13 inquire of both the product manager and the</p> <p>14 national account manager?</p> <p>15 A. Depends on the circumstances and the</p> <p>16 product.</p> <p>17 Q. Okay. Did you ever have any</p> <p>18 difficulty in receiving responses either from</p> <p>19 product managers or national account managers</p> <p>20 with respect to inquiries that you made</p> <p>21 regarding peculiar orders?</p> <p>22 A. Sometimes we'd have to send them a</p> <p>23 reminder e-mail if they were travelling that the</p> <p>24 order was still on hold and we were awaiting</p>	<p style="text-align: right;">Page 193</p> <p>1 Q. Okay. Do you know who Cathy Stewart</p> <p>2 was?</p> <p>3 A. Yes.</p> <p>4 Q. Who was she?</p> <p>5 A. She was a customer service manager.</p> <p>6 Q. Did you interact with her from time to</p> <p>7 time?</p> <p>8 A. Yes.</p> <p>9 Q. And she had customer service reps who</p> <p>10 reported to her, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And your March 5, 2012 e-mail, one of</p> <p>13 the persons that you address it to is Victor</p> <p>14 Borelli, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And did you deal with Mr. Borelli from</p> <p>17 time to time?</p> <p>18 A. Yes.</p> <p>19 Q. Did Ms. Stewart ever express to you,</p> <p>20 that you can recall, that one or more of the</p> <p>21 customer service reps who reported to her had</p> <p>22 expressed the view that Mr. Borelli would tell</p> <p>23 them anything to get a sale?</p> <p>24 MR. O'CONNOR: Objection to form.</p>

<p style="text-align: right;">Page 194</p> <p>1 A. Not that I remember.</p> <p>2 BY MR. GOTTO:</p> <p>3 Q. Okay. You can set that aside.</p> <p>4 (Whereupon, Mallinckrodt-Spaulding-18</p> <p>5 was marked for identification.)</p> <p>6 BY MR. GOTTO:</p> <p>7 Q. We've marked as Exhibit 18 a two-page</p> <p>8 e-mail thread beginning at Bates</p> <p>9 MNK-T1_0000280632. Take a moment to look at</p> <p>10 those e-mails, if you would.</p> <p>11 (Witness reviewing document.)</p> <p>12 A. Okay.</p> <p>13 Q. And do you recall this e-mail</p> <p>14 exchange?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. What do you recall of that?</p> <p>17 A. Karen was alerting me to some -- she</p> <p>18 had compiled a timeline and had sent me the</p> <p>19 timeline, and then was letting me know that all</p> <p>20 the orders had been reviewed by the customer</p> <p>21 service manager, and then later on in the e-mail</p> <p>22 she corrects terminology listed below.</p> <p>23 Q. Okay. In Ms. Harper's e-mail, she --</p> <p>24 the first e-mail, October 31, "In an effort to</p>	<p style="text-align: right;">Page 196</p> <p>1 Q. Okay. And in Ms. Harper's October 31</p> <p>2 e-mail, she says "during the last two years, all</p> <p>3 Peculiar Orders...were deemed to be okay and</p> <p>4 none rose to the level of Peculiar."</p> <p>5 Do you know if she meant there that</p> <p>6 none rose to the level of suspicious?</p> <p>7 MR. O'CONNOR: Objection.</p> <p>8 A. She did. In the earlier e-mail above</p> <p>9 she clarifies that --</p> <p>10 BY MR. GOTTO:</p> <p>11 Q. Okay.</p> <p>12 A. -- she meant none rose to the level of</p> <p>13 suspicious.</p> <p>14 Q. Okay. And that's consistent with your</p> <p>15 recollection you've already testified to in</p> <p>16 terms of orders being identified as suspicious,</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. She goes on to say "It is significant</p> <p>20 to note that neither Sunrise or Harvard</p> <p>21 triggered the algorithms that were in place for</p> <p>22 direct customers because we were looking at</p> <p>23 overall purchase trends for each distributor,</p> <p>24 not reviewing where the distributors were</p>
<p style="text-align: right;">Page 195</p> <p>1 provide you with as much information as</p> <p>2 possible, I have attached a (lengthy) chronology</p> <p>3 of events relating to Mallinckrodt Suspicious</p> <p>4 Order Monitoring."</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. Let me hand you what we've marked as</p> <p>8 Exhibit 19, and you can tell me if that's the</p> <p>9 attachment.</p> <p>10 (Whereupon, Mallinckrodt-Spaulding-19</p> <p>11 was marked for identification.)</p> <p>12 BY MR. GOTTO:</p> <p>13 Q. Exhibit 19 is a multi-page document</p> <p>14 beginning at page MNK-T1_0000477900. Can you</p> <p>15 tell me if that's the chronology that Ms. Harper</p> <p>16 is referring to?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And you're familiar with that</p> <p>19 chronology, right?</p> <p>20 A. At a high level, yes.</p> <p>21 Q. Okay. Did you have occasion ever to</p> <p>22 provide this chronology to DEA?</p> <p>23 A. We met in -- we went and met with DEA.</p> <p>24 We didn't provide a document, I don't recall.</p>	<p style="text-align: right;">Page 197</p> <p>1 sending our product (and our program met CFR</p> <p>2 requirements)."</p> <p>3 And is that the phenomenon you</p> <p>4 testified about earlier today, looking at ship</p> <p>5 to rather than bill to?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. No, that's different.</p> <p>8 BY MR. GOTTO:</p> <p>9 Q. Okay. In what way is this different?</p> <p>10 A. So Karen is referring to downstream</p> <p>11 customers, so those wouldn't have triggered</p> <p>12 because we were only looking at our direct</p> <p>13 shipments to Sunrise and to Harvard. We weren't</p> <p>14 looking at where Harvard was shipping, or</p> <p>15 Sunrise.</p> <p>16 Q. Okay. And she indicates in the last</p> <p>17 sentence of that paragraph that the program has</p> <p>18 now been expanded in October of 2010 to look at</p> <p>19 customers' customers, correct?</p> <p>20 A. Based on this e-mail, yes.</p> <p>21 Q. Okay. And was that your recollection</p> <p>22 as well, that in late 2010 the SOM program was</p> <p>23 expanded to include a review of Mallinckrodt's</p> <p>24 customers' customers?</p>

<p style="text-align: right;">Page 198</p> <p>1 MR. O'CONNOR: Objection to form.</p> <p>2 A. Only based on this e-mail.</p> <p>3 BY MR. GOTTO:</p> <p>4 Q. You don't otherwise recall that?</p> <p>5 A. No.</p> <p>6 Q. Can you recall at any time in</p> <p>7 connection with suspicious order monitoring you</p> <p>8 personally reviewing information regarding</p> <p>9 Mallinckrodt's customers' customers?</p> <p>10 A. I was involved in reviewing</p> <p>11 chargebacks, but I don't remember when that</p> <p>12 started.</p> <p>13 Q. And that would have given you</p> <p>14 information about Mallinckrodt's customers'</p> <p>15 customers, right?</p> <p>16 A. If they applied and participated in</p> <p>17 chargebacks, yes.</p> <p>18 Q. Okay.</p> <p>19 (Whereupon, Mallinckrodt-Spaulding-20</p> <p>20 was marked for identification.)</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. We've marked as Exhibit 20 a two-page</p> <p>23 document beginning at Bates MNK-T1_0002357150,</p> <p>24 appear to be notes from the 11/1/10 meeting at</p>	<p style="text-align: right;">Page 200</p> <p>1 Q. And what was the reason that you</p> <p>2 wanted to explain the SOM program to the DEA at</p> <p>3 this point?</p> <p>4 A. I don't remember specifically.</p> <p>5 Q. Under "General Feedback from DEA</p> <p>6 Albany," it states "The direct and indirect</p> <p>7 customer data was presented to DEA. DEA was</p> <p>8 alarmed by the data but not surprised."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And were these your notes or</p> <p>12 Mr. Nikolaus's notes?</p> <p>13 A. They were my notes.</p> <p>14 Q. Okay. So when you say they were</p> <p>15 alarmed by the data but not surprised, what do</p> <p>16 you mean? How did they express that?</p> <p>17 A. I remember them looking at the data</p> <p>18 and going "wow." And then a comment by someone</p> <p>19 that was in attendance, I don't remember</p> <p>20 specifically who, saying they're not surprised</p> <p>21 by that.</p> <p>22 Q. What was your reason for providing the</p> <p>23 direct and indirect customer data to the DEA at</p> <p>24 this time?</p>
<p style="text-align: right;">Page 199</p> <p>1 the DEA Albany office.</p> <p>2 Do you recognize those notes?</p> <p>3 A. Yes.</p> <p>4 Q. And it indicates that you and</p> <p>5 Mr. Nikolaus attended the meeting, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And you recall the meeting, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Can you recall other similar meetings</p> <p>10 with the DEA Albany office?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. Similar, meeting with them about this</p> <p>13 topic or about any topic?</p> <p>14 BY MR. GOTTO:</p> <p>15 Q. Well, back that up.</p> <p>16 Did you have regular meetings at the</p> <p>17 DEA's Albany office?</p> <p>18 A. No.</p> <p>19 Q. Okay. So was this meeting requested</p> <p>20 by the DEA?</p> <p>21 A. No, this meeting was requested by</p> <p>22 Mallinckrodt.</p> <p>23 Q. And for what purpose?</p> <p>24 A. To explain to them our SOM program.</p>	<p style="text-align: right;">Page 201</p> <p>1 A. Because we were incorporating</p> <p>2 chargebacks into our SOM program, so when</p> <p>3 explaining the SOM program we showed them what</p> <p>4 we were looking at direct data, and what we were</p> <p>5 looking at indirect data.</p> <p>6 Q. And was this the first time that you</p> <p>7 began to look at the direct and indirect</p> <p>8 customer data?</p> <p>9 MR. O'CONNOR: Objection to form.</p> <p>10 BY MR. GOTTO:</p> <p>11 Q. In this time frame?</p> <p>12 A. I don't remember when I started. We</p> <p>13 were doing it at this time.</p> <p>14 Q. If you look at Exhibit 18, I believe</p> <p>15 Ms. Harper indicated in her e-mail dated</p> <p>16 October 31 that "the program was expanded within</p> <p>17 the last month to our customers' customers." So</p> <p>18 would that indicate that this is -- that the</p> <p>19 meeting occurred on November 1st, right, so</p> <p>20 would that indicate that at this time this was</p> <p>21 when you first began looking at the indirect</p> <p>22 customer data?</p> <p>23 MR. O'CONNOR: Objection to form.</p> <p>24 A. Based on this e-mail. But I don't</p>



<p style="text-align: right;">Page 202</p> <p>1 remember.</p> <p>2 BY MR. GOTTO:</p> <p>3 Q. Okay. You can set that aside.</p> <p>4 (Whereupon, Mallinckrodt-Spaulding-21</p> <p>5 was marked for identification.)</p> <p>6 BY MR. GOTTO:</p> <p>7 Q. Exhibit 21 is a single-page e-mail</p> <p>8 thread MNK-T1_0000270021. Take a look at that</p> <p>9 e-mail, appears to be an e-mail from you to</p> <p>10 Heather White, and tell me if you recognize it.</p> <p>11 (Witness reviewing document.)</p> <p>12 A. Okay.</p> <p>13 Q. Do you recognize that e-mail?</p> <p>14 A. Yes.</p> <p>15 Q. And Heather White was at the DEA,</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. And what was your reason for providing</p> <p>19 the information in your November 30th e-mail to</p> <p>20 Ms. White?</p> <p>21 A. Because when we spoke to her at the</p> <p>22 on-site meeting we advised that we were sending</p> <p>23 out distributor letters based on the data that</p> <p>24 we had reviewed.</p>	<p style="text-align: right;">Page 204</p> <p>1 Q. Would that information have been</p> <p>2 pertinent to your audit at that time?</p> <p>3 A. If Cedardale had been suspended</p> <p>4 shipping to pharmacies?</p> <p>5 Q. If Cedardale itself had determined</p> <p>6 that it would suspend certain of its customers.</p> <p>7 A. We would have documented that in our</p> <p>8 audit notes.</p> <p>9 Q. That would have been of interest to</p> <p>10 you?</p> <p>11 A. It would have been documented.</p> <p>12 Q. But you don't recall being aware of</p> <p>13 that as you sit here today?</p> <p>14 A. No.</p> <p>15 Q. Do you recall if you made an inquiry</p> <p>16 in that regard as part of the audit?</p> <p>17 A. I'd have to look at my notes.</p> <p>18 Q. Okay.</p> <p>19 (Whereupon, Mallinckrodt-Spaulding-22</p> <p>20 was marked for identification.)</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. Exhibit 22 is a two-page e-mail thread</p> <p>23 beginning at Bates MNK-T1_0001519526. Take a</p> <p>24 moment and tell me if you recognize those</p>
<p style="text-align: right;">Page 203</p> <p>1 Q. And you talk about three distributors,</p> <p>2 Masters, KeySource, Cedardale. I think you</p> <p>3 indicated earlier in your testimony today that</p> <p>4 those are three distributors that were audited</p> <p>5 in approximately this time frame, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And ultimately all of those</p> <p>8 distributors had their DEA licenses terminated,</p> <p>9 didn't they?</p> <p>10 MR. O'CONNOR: Object to the form.</p> <p>11 A. I don't know that they were</p> <p>12 terminated.</p> <p>13 BY MR. GOTTO:</p> <p>14 Q. At least suspended?</p> <p>15 A. I know of Masters and KeySource. I</p> <p>16 don't remember Cedardale.</p> <p>17 Q. Do you recall -- you testified a</p> <p>18 little earlier today regarding the Cedardale</p> <p>19 audit. Do you recall if at the time of the</p> <p>20 Cedardale audit you had any information</p> <p>21 regarding whether Cedardale had suspended sales</p> <p>22 to any of its existing customers?</p> <p>23 A. I don't remember having any of that</p> <p>24 information at that time.</p>	<p style="text-align: right;">Page 205</p> <p>1 e-mails.</p> <p>2 (Witness reviewing document.)</p> <p>3 A. Okay.</p> <p>4 Q. Do you recognize those e-mails?</p> <p>5 A. I don't remember them, no.</p> <p>6 Q. Okay. The main e-mail, the August 6,</p> <p>7 2012 e-mail from you to Heather White, "is a</p> <p>8 list of distributors that we have met with in</p> <p>9 person or by telephone to discuss SOM issues</p> <p>10 within the last twelve months."</p> <p>11 Do you recall having those personal or</p> <p>12 telephonic meetings with the listed</p> <p>13 distributors?</p> <p>14 A. I remember having telecons, yes.</p> <p>15 Q. And what would cause you to have a</p> <p>16 personal or telephonic meeting with a</p> <p>17 distributor regarding SOM issues?</p> <p>18 A. So the SOM team would decide whether</p> <p>19 we needed to do an on-site audit or if we could</p> <p>20 do a telecon in which we'd review with them</p> <p>21 their orders and the data, their chargeback</p> <p>22 data.</p> <p>23 Q. And what is it that would cause the</p> <p>24 team to decide that such an audit or</p>

<p style="text-align: right;">Page 206</p> <p>1 teleconference was required?</p> <p>2 A. I don't remember any specifics why we</p> <p>3 would.</p> <p>4 Q. Of the parties listed in this e-mail,</p> <p>5 do you recall how any of these were personal</p> <p>6 meetings as compared to teleconferences?</p> <p>7 A. In 2012, no, because some of the</p> <p>8 on-site audits were conducted by people in</p> <p>9 corporate, so I don't remember specific. I</p> <p>10 remember doing -- I was only involved in the</p> <p>11 Cedardale audit on-site, and I remember being</p> <p>12 involved in telecons, but which ones</p> <p>13 specifically, I'd have to look at notes.</p> <p>14 MR. GOTTO: Okay. Why don't we take a</p> <p>15 break.</p> <p>16 THE VIDEOGRAPHER: The time is</p> <p>17 2:28 p.m., and we're off the record.</p> <p>18 (Whereupon, a recess was taken.)</p> <p>19 THE VIDEOGRAPHER: The time is</p> <p>20 2:42 p.m., and we're on the record.</p> <p>21 (Whereupon, Mallinckrodt-Spaulding-23</p> <p>22 was marked for identification.)</p> <p>23 BY MR. GOTTO:</p> <p>24 Q. Ms. Spaulding, we've marked as</p>	<p style="text-align: right;">Page 208</p> <p>1 centralized place between all three sites to</p> <p>2 document any correspondence that we had with</p> <p>3 DEA, so I feel the need to clarify that even</p> <p>4 though we called them SOM contacts or inquiry,</p> <p>5 they were not always indicative of a suspicious</p> <p>6 order. It was part of the overall umbrella</p> <p>7 program of suspicious order monitoring.</p> <p>8 Q. Okay. And so what would be an example</p> <p>9 of something that's under that overall umbrella</p> <p>10 but was not indicative of the suspicious order?</p> <p>11 A. So, for example, in this report 11-01,</p> <p>12 this was the ARCOS unit contacting me about two</p> <p>13 NDC errors -- or I'm sorry, contacting Mary</p> <p>14 Lewis and Webster Groves. One that was specific</p> <p>15 to me was line 5, so report 11-03 was to contact</p> <p>16 DI Heather White because we had a complaint</p> <p>17 about Methadose 40-milligram bottle complaints.</p> <p>18 Q. Okay. And then one of the attachments</p> <p>19 is -- it's called a DEA Suspicious Order</p> <p>20 Monitoring Report?</p> <p>21 A. Yes.</p> <p>22 Q. And what is that document?</p> <p>23 A. So this was a template that we were</p> <p>24 using to how we would document a formal</p>
<p style="text-align: right;">Page 207</p> <p>1 Exhibit 23 a multi-page document beginning at</p> <p>2 Bates MNK-T1_0000289371. It's an e-mail along</p> <p>3 with an attachment. Please take a look at that</p> <p>4 and tell me if you recognize it.</p> <p>5 I guess it actually has a series of</p> <p>6 attachments, I should say.</p> <p>7 (Witness reviewing document.)</p> <p>8 A. Okay.</p> <p>9 Q. Do you recognize those documents?</p> <p>10 A. No, I don't remember them, only based</p> <p>11 on the e-mail.</p> <p>12 Q. Okay. So your e-mail, your</p> <p>13 October 18th e-mail to Ms. Harper, any reason to</p> <p>14 doubt you sent that?</p> <p>15 A. No.</p> <p>16 Q. And you make reference in your e-mail</p> <p>17 to "tried several different ways to make a</p> <p>18 report that we could use across sites to be</p> <p>19 consistent in our practices."</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. So can you describe for me what you</p> <p>23 were trying to accomplish in this regard?</p> <p>24 A. So we were looking to make a</p>	<p style="text-align: right;">Page 209</p> <p>1 suspicious order.</p> <p>2 Q. Okay. And so this is not a DEA form,</p> <p>3 right? This is something you -- or Mallinckrodt</p> <p>4 created?</p> <p>5 A. Correct. This one is -- it says up at</p> <p>6 the top is an example only.</p> <p>7 Q. Okay. You can set that aside.</p> <p>8 (Whereupon, Mallinckrodt-Spaulding-24</p> <p>9 was marked for identification.)</p> <p>10 BY MR. GOTTO:</p> <p>11 Q. Exhibit 24 is a multi-page document</p> <p>12 beginning at MNK-T1_0000282467, appears to be an</p> <p>13 e-mail you prepared attaching the notes of an</p> <p>14 HDMA conference that you attended.</p> <p>15 Could you take a look at that and</p> <p>16 confirm for me, if you can, that that's what the</p> <p>17 exhibit consists of?</p> <p>18 (Witness reviewing document.)</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Do you recall this conference?</p> <p>21 A. Vaguely. Not in detail, but yes.</p> <p>22 Q. Did you make a practice of keeping</p> <p>23 notes like these at each conference you went to</p> <p>24 and then memorializing them?</p>

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1 A. Not every conference, only if I was  
2 asked to produce a conference or a trip report.  
3 Q. Okay. And who would have asked you to  
4 do that?  
5 A. My manager at the time.  
6 Q. If you turn to the next-to-last page  
7 of the document, the one that ends in Bates  
8 473 -- I guess actually starting at the bottom  
9 of the third-to-last page that begins at Bates  
10 472, there's a reference to a presentation by a  
11 David Durkin regarding controlled substance  
12 monitoring, 2011 update.  
13 Do you see that?  
14 A. Yes.  
15 Q. And the main bullet items, the third  
16 one on the following page is "Reviewed the  
17 12/2007 DEA Letter to registrants."  
18 Do you see that?  
19 A. Give me one moment, please.  
20 Q. Sure.  
21 (Witness reviewing document.)  
22 A. I'm sorry, which bullet were you --  
23 Q. There's -- the second main bullet on  
24 the page that ends in 473 says "Reviewed the

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1 12/2007 DEA Letter to registrants."  
2 Do you see that?  
3 A. Yes.  
4 Q. And that's the letter from  
5 Mr. Rannazzisi that we looked at a little  
6 earlier today, correct?  
7 A. I'm not looking at the date, but I  
8 believe so, yes.  
9 Q. Okay. You can set that aside.  
10 (Whereupon, Mallinckrodt-Spaulding-25  
11 was marked for identification.)  
12 BY MR. GOTTO:  
13 Q. Exhibit 25 is a multi-page document  
14 bearing Bates MNK-T1\_0000283244, appears to be  
15 an e-mail you prepared transmitting notes you  
16 took at a Buzzeo webinar in April of 2011. If  
17 you could take a look at that and confirm for me  
18 that that's what those materials are.  
19 A. Yes.  
20 Q. Okay. Do you recall this particular  
21 webinar?  
22 A. Not this one, no.  
23 Q. The notes that you took here, did you  
24 have occasion to go over these with Ms. Harper

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1 or anyone else at Mallinckrodt?  
2 A. Go over them? I sent them to her, but  
3 I didn't -- I don't know that I reviewed or  
4 discussed them with her.  
5 Q. Okay. On the second page of your  
6 notes up at the top where it says "SOM System  
7 Recommendations - Total SOM Solution," do you  
8 see that?  
9 A. Yes.  
10 Q. The second item is "Determine  
11 legitimacy before shipping for each and every  
12 order."  
13 Do you see that?  
14 A. Yes.  
15 Q. Did you understand at this time that  
16 an SOM program -- that part of an effective SOM  
17 program should be that before an order that was  
18 identified -- that was questioned in any way  
19 shipped, a determination needed to be made as to  
20 whether or not it was suspicious?  
21 MR. O'CONNOR: Objection to form.  
22 A. At this time back in 2011 did I know  
23 that?  
24 BY MR. GOTTO:

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1 Q. Yes.  
2 A. I don't know if I knew it at the time.  
3 I mean, I understood what it says when they  
4 spoke of it.  
5 Q. Okay. Do you have an understanding as  
6 to whether in this time frame in 2011  
7 Mallinckrodt had procedures in place to assure  
8 that orders that had been identified as peculiar  
9 or unusual would not be shipped until it was  
10 determined whether or not there would be -- they  
11 were suspicious?  
12 MR. O'CONNOR: Objection to form.  
13 A. So based on our review of documents  
14 prior in 2010, we discussed that we were  
15 reviewing orders before shipping.  
16 BY MR. GOTTO:  
17 Q. Do you know if there were ever  
18 occasions when an order that was identified as  
19 peculiar or unusual was shipped before the  
20 determination was made as to whether it was  
21 suspicious?  
22 A. Not by me, but I wasn't doing -- I'm  
23 not aware. I wasn't doing the review.  
24 Q. Do you recall in 2010 there being a

<p style="text-align: right;">Page 214</p> <p>1 change to the algorithm whereby the comparison  2 of an order to the prior year's ordering pattern  3 was changed from whether it was more than two  4 times the average to whether it was more than  5 three times the average?  6 A. I remember that there was a change. I  7 don't remember whether it was specifically in  8 2010 or not.  9 Q. Okay. But you do remember that 2X to  10 3X change being made at some point?  11 A. Yes.  12 Q. Do you remember what the reason was  13 for that change?  14 A. No.  15 Q. Were you involved in the decision to  16 make that change?  17 A. I would have been on the SOM team that  18 discussed the change, but it would have been  19 approved by the management.  20 Q. Do you remember who suggested the  21 change?  22 A. No.  23 Q. And you don't remember any of the  24 reasons that were offered in support of it?</p>	<p style="text-align: right;">Page 216</p> <p>1 Q. Right. But you were, as of November,  2 2010, you were reviewing chargeback data as part  3 of the SOM process, correct?  4 A. Yes.  5 Q. And so my question is, once you  6 started reviewing the chargeback data, did that  7 result in the identification of any orders as  8 peculiar or unusual or suspicious under the SOM  9 program?  10 A. No, because there's no way to directly  11 tie a chargeback order credit to a direct order.  12 Q. And so how was the chargeback data  13 used as part of the SOM program from and after  14 November of 2010?  15 A. To review if a downstream customer, so  16 a customer's customer, may pose a risk to bring  17 that attention to the down-direct customer.  18 Q. And how would you identify as part of  19 the chargeback review the potential for that  20 downstream customer to pose a risk?  21 A. So based on the red flags and the  22 enforcement action in comments from DEA at  23 training sessions through the DEA seminars, we  24 developed a red flags list, and we would look at</p>
<p style="text-align: right;">Page 215</p> <p>1 A. No, not specifically.  2 (Whereupon, Mallinckrodt-Spaulding-26  3 was marked for identification.)  4 BY MR. GOTTO:  5 Q. Exhibit 26 is a two-page document  6 beginning at Bates MNK-T1_0000288483, appears to  7 be a letter from you to Heather White at the  8 DEA. And take a look and tell me if you can  9 confirm that that's a letter that you sent on or  10 about November 1 of 2010.  11 (Witness reviewing document.)  12 A. Yes, this is a letter I sent.  13 Q. Okay. And this is notifying Ms. White  14 of the inclusion in the SOM program of review of  15 chargeback data, correct?  16 A. Yes.  17 Q. And do you recall, after the  18 chargeback data review was included as part of  19 the SOM program, were there orders that were  20 identified as peculiar or unusual solely as a  21 result of the chargeback review?  22 A. So I don't think I understand.  23 Chargeback are not orders. Chargeback are  24 downstream.</p>	<p style="text-align: right;">Page 217</p> <p>1 chargebacks to see if a pharmacy had a large  2 quantity, we would then ask the distributor for  3 due diligence and ask them to check for any of  4 these red flags as part of the review.  5 Q. So is it fair to say Mallinckrodt  6 itself would not take any action directly with  7 respect to this indirect customer, but would  8 instead provide information to Mallinckrodt's  9 direct customer?  10 MR. O'CONNOR: Objection to form.  11 A. We would do both. So we would work  12 with the distributor to bring to their attention  13 that we're potentially seeing chargebacks,  14 because a distributor would only see what they  15 sold, they wouldn't see if there was other  16 distributors selling to them. And if the SOM  17 team determined that the pharmacy was a  18 significant risk, they would issue a restriction  19 in which that pharmacy could no longer apply for  20 chargebacks.  21 BY MR. GOTTO:  22 Q. Okay. So the pharmacy would -- it  23 could continue to buy from a Mallinckrodt  24 distributor, but it could not apply for a</p>

<p style="text-align: right;">Page 218</p> <p>1 chargeback?</p> <p>2 A. Correct.</p> <p>3 Q. So the chargebacks, were they applied</p> <p>4 for by the pharmacies or by the distributor?</p> <p>5 A. The chargeback is applied by the</p> <p>6 distributor to Mallinckrodt on behalf of the</p> <p>7 pharmacy.</p> <p>8 Q. So it would have been possible for</p> <p>9 Mallinckrodt to inform the distributor that</p> <p>10 sales should not be made to that pharmacy, as</p> <p>11 compared to stating that Mallinckrodt would not</p> <p>12 pay chargebacks to that -- related to that</p> <p>13 pharmacy, correct?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. No, we can't dictate who a distributor</p> <p>16 sells to and who they don't sell to.</p> <p>17 BY MR. GOTTO:</p> <p>18 Q. So if you knew that a distributor, for</p> <p>19 example, was selling to a non-registrant, you</p> <p>20 could tell the distributor, you need to stop</p> <p>21 doing that or we can't sell to you anymore,</p> <p>22 correct?</p> <p>23 A. If we knew that they were selling to a</p> <p>24 non-DEA registrant, I believe we would alert DEA</p>	<p style="text-align: right;">Page 220</p> <p>1 get Mallinckrodt product.</p> <p>2 Q. And that's true, though, if you say</p> <p>3 we're not going to honor chargebacks, that</p> <p>4 pharmacy can continue to buy Mallinckrodt</p> <p>5 products even through that distributor, just not</p> <p>6 going to -- the chargeback won't be honored,</p> <p>7 correct?</p> <p>8 A. Correct. It's a financial</p> <p>9 disincentive not to sell Mallinckrodt product,</p> <p>10 but we can't say who they can or can't sell to.</p> <p>11 Q. Was the result of any chargeback data</p> <p>12 review ever provided to the DEA?</p> <p>13 A. Can you say at that again, please?</p> <p>14 Q. Yes.</p> <p>15 So you engaged in -- from November,</p> <p>16 2010 forward you were reviewing chargeback data</p> <p>17 as part of an evaluation as to whether there</p> <p>18 were red flags with respect to some indirect --</p> <p>19 with respect to indirect customers, correct?</p> <p>20 A. Yes. If we restricted a pharmacy from</p> <p>21 chargebacks, we notified DEA.</p> <p>22 Q. Okay. And was there any follow-up</p> <p>23 from DEA that you can recall when there was any</p> <p>24 such notification given?</p>
<p style="text-align: right;">Page 219</p> <p>1 to that.</p> <p>2 Q. And so if you knew that a distributor</p> <p>3 was selling to a pharmacy as to which there was</p> <p>4 sufficient red flags to where Mallinckrodt</p> <p>5 decided that it would no longer pay chargebacks</p> <p>6 with respect to that pharmacy, Mallinckrodt</p> <p>7 could have notified the distributor that if the</p> <p>8 distributor continued to sell to that pharmacy</p> <p>9 Mallinckrodt wouldn't sell to the distributor</p> <p>10 anymore?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 BY MR. GOTTO:</p> <p>13 Q. Right?</p> <p>14 A. No, because then we could potentially</p> <p>15 jeopardize legitimate people from not getting</p> <p>16 their medicines. We prohibited the chargebacks</p> <p>17 as a financial disincentive to not sell</p> <p>18 Mallinckrodt to a pharmacy that we considered a</p> <p>19 risk. But we can't control the distributors and</p> <p>20 who they sell to. We have no influence</p> <p>21 whatsoever on who the customer base of any one</p> <p>22 distributor is. And if we had -- say you can't</p> <p>23 sell to that pharmacy anymore, that pharmacy</p> <p>24 could potentially go to another distributor and</p>	<p style="text-align: right;">Page 221</p> <p>1 A. Not that I can think of.</p> <p>2 Q. What was the nature of the</p> <p>3 notification? What did you tell DEA?</p> <p>4 A. We have a letter that we would notify</p> <p>5 sent to DEA saying these pharmacies have been</p> <p>6 restricted from Mallinckrodt chargebacks because</p> <p>7 they exhibit indicators of diversion.</p> <p>8 Q. You can set that aside.</p> <p>9 (Whereupon, Mallinckrodt-Spaulding-27</p> <p>10 was marked for identification.)</p> <p>11 BY MR. GOTTO:</p> <p>12 Q. Exhibit 27 is a multi-page document</p> <p>13 beginning at Bates MNK-T1_0000422189. It's an</p> <p>14 e-mail thread from late 2010 into January of</p> <p>15 2011. Take a moment and tell me if you</p> <p>16 recognize those e-mails.</p> <p>17 (Witness reviewing document.)</p> <p>18 A. Okay.</p> <p>19 Q. Do you recognize these e-mails?</p> <p>20 A. No.</p> <p>21 Q. Okay. So the earliest e-mails in the</p> <p>22 thread are an exchange between Ms. Harper and</p> <p>23 Carol Svejkosky --</p> <p>24 A. Yeah, Svejkosky.</p>



<p style="text-align: right;">Page 222</p> <p>1 Q. Thank you. S-V-E-J-K-O-S-K-Y, just  2 like it sounds.  3 -- in which Ms. Harper is requesting  4 certain state concentration and customer  5 sourcing data, correct?  6 A. Yes.  7 Q. And is that data that ultimately you  8 came to be supplied with regularly?  9 A. Yes.  10 Q. Okay. And did that become part of the  11 SOM program, reviewing that data on a monthly  12 basis?  13 A. Yes.  14 Q. What was the state concentration  15 report that Ms. Harper requests?  16 A. It looks at oxycodone 50-milligram and  17 oxycodone 30-milligram by state instead of by  18 pharmacy.  19 Q. And do you know what the reason was  20 for conducting that review?  21 A. Based on at this time the enforcement  22 action and the knowledge around Florida and  23 other states being of concern.  24 Q. Okay. All right. You can set that</p>	<p style="text-align: right;">Page 224</p> <p>1 A. No, I couldn't guess what she was  2 referring to.  3 Q. Okay. So if you look at the first  4 e-mail in the thread from Thanh Churchin,  5 "Susan, can you check on this lot number for  6 me," giving a case number. "The lot number came  7 from a trash pull that IRS did."  8 Do you know what "lot number" means in  9 this context?  10 A. Yes. It's the lot number that  11 Mallinckrodt produced for that particular batch.  12 Q. Okay. And what would be the reason  13 for using that lot number?  14 MR. O'CONNOR: Objection to form.  15 BY MR. GOTTO:  16 Q. What information would that give you?  17 A. We could trace the lot number to see  18 who we sold it to, but then they would have to  19 go to who we sold it to to trace who they sold  20 it to.  21 Q. Okay. And so turning back to  22 Ms. White's e-mail where she says "I know the  23 standard answer regarding lot numbers," was the  24 standard answer that you would give that</p>
<p style="text-align: right;">Page 223</p> <p>1 aside.  2 (Whereupon, Mallinckrodt-Spaulding-28  3 was marked for identification.)  4 BY MR. GOTTO:  5 Q. Exhibit 28 is a two-page e-mail thread  6 beginning at Bates MNK-T1_0000485790, e-mails  7 from November of 2010. Take a moment and tell  8 me if you recall these e-mails.  9 (Witness reviewing document.)  10 A. Okay.  11 Q. Do you recognize these e-mails?  12 A. I don't remember them.  13 Q. Okay. If you look at Ms. White's  14 e-mail at the bottom of the first page to you on  15 November 18th, she says "I know the standard  16 answer regarding lot numbers. Can you please  17 tell me which distributors this was sent to and  18 if you had any chargebacks for the product in  19 the Fort Lauderdale area? We can get an  20 Administrative Subpoena if you need one."  21 Do you see that?  22 A. Yes.  23 Q. So do you know what she meant by "the  24 standard answer regarding lot numbers"?</p>	<p style="text-align: right;">Page 225</p> <p>1 information if there was -- in response to a  2 subpoena?  3 A. I don't know what she meant.  4 Q. Do you recall ever informing Ms. White  5 or anyone else at the DEA that certain  6 information they sought would be provided only  7 in response to a subpoena?  8 A. We usually request a subpoena if they  9 want anything in writing, so it's pretty  10 standard.  11 Q. Okay. And so there would be times  12 when you would give them verbal information, but  13 if they wanted that information in writing you'd  14 tell them they needed to issue a subpoena?  15 A. Not during a -- not a shipping history  16 report.  17 Q. You would not require a subpoena for  18 that?  19 A. No. I'm sorry. We would require -- I  20 would not give them that information verbally.  21 Q. Okay. And what's the reason for that?  22 A. Just any information that's provided  23 to DEA always goes through our legal department.  24 Q. Well, there was certain information</p>

<p style="text-align: right;">Page 226</p> <p>1 you would give DEA verbally, that if they asked          2 for it in writing you'd require a subpoena,          3 correct?          4 A. The information that we would give to          5 them verbally would be routine information that          6 they would ask regarding a process or a high          7 level question. Anything that was documented or          8 in detail like a shipping report would require a          9 subpoena.          10 Q. Okay. So your November 18th e-mail to          11 Karen Harper says "I can run a report on where          12 we ship this lot number to. Does the chargeback          13 system refer to lot numbers? If so" you can get          14 a report, please. I'm sorry, "If so, can you          15 get a report please."          16 So I take it at this time in November          17 of 2010 you didn't know if the chargeback system          18 contained the lot numbers for orders, correct?          19 A. Correct. Because what we looked at          20 were reports that were generated from the          21 chargeback system.          22 Q. Okay. And so the -- what information          23 were you able to determine from reviewing a lot          24 number?</p>	<p style="text-align: right;">Page 228</p> <p>1 Q. Do you recall that e-mail?          2 A. Vaguely, yes.          3 Q. Okay. And then you respond to him on          4 July 6th "Would you like me to run a lot trace          5 report ASAP?"          6 A. Correct.          7 Q. And he responds "Yes." You run the          8 report. Is the attachment to the e-mail the          9 report?          10 A. Yes.          11 Q. And you say in your e-mail total          12 quantity of bottles. You say "Lot beam for          13 release."          14 What does that mean?          15 A. It means when it is released from our          16 quality control labs and able to be shipped to          17 market.          18 Q. Okay. And then "Shipped from DC."          19 What is DC?          20 A. Distribution center.          21 Q. Okay. On the dates, "and entire lot          22 is depleted. 8 customers in total, 1 in          23 Florida."          24 And then the eight customers are</p>
<p style="text-align: right;">Page 227</p> <p>1 A. Where we shipped it to.          2 (Whereupon, Mallinckrodt-Spaulding-29          3 was marked for identification.)          4 BY MR. GOTTO:          5 Q. Exhibit 29 is a multi-page document          6 beginning at Bates MNK-T1_0000561060, appears to          7 be an e-mail exchange between you and          8 Mr. Ratliff concerning a lot trace report. Take          9 a look at those e-mails, tell me if you          10 recognize them.          11 (Witness reviewing document.)          12 A. Okay.          13 Q. Okay. And so the first e-mail in the          14 thread is from Mr. Ratliff, down at the bottom          15 of the first page onto the second page, from          16 Mr. Ratliff to you and Mr. Nikolaus, where he          17 says "Oxy, lot," and gives a number, "is being          18 transported from Florida to Eastern Tennessee in          19 fairly significant quantities. They have          20 original bottles and are currently looking for          21 the source of loss in Florida. I will be          22 receiving additional information soon."          23 Do you see that?          24 A. Yes.</p>	<p style="text-align: right;">Page 229</p> <p>1 listed on the attachment, correct?          2 A. Yes.          3 Q. And so the attachment, is this typical          4 of the information that a lot trace report would          5 give you?          6 A. It's the exact information.          7 Q. Okay. You can set that aside.          8 (Whereupon, Mallinckrodt-Spaulding-30          9 was marked for identification.)          10 BY MR. GOTTO:          11 Q. Exhibit 30 is a two-page document          12 beginning at Bates MNK-T1_0000371673, and          13 appears to be an e-mail exchange between you and          14 Ms. Harper in June of 2010 concerning a DEA and          15 local law enforcement inquiry. Tell me if you          16 recognize those e-mails.          17 (Witness reviewing document.)          18 A. Okay.          19 Q. Do you recognize those e-mails?          20 A. Yes.          21 Q. Okay. So in your June 17th e-mail to          22 Ms. Harper, in the first paragraph you say that          23 in recent months you "received several inquiries          24 from both local law enforcement and DEA...in the</p>

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1 State of Florida and surrounding states  
 2 regarding lot trace shipping histories."  
 3 You go on a little later in the  
 4 paragraph to say "In many of these inquiries, I  
 5 noticed that Sunrise Wholesalers was one of our  
 6 customers who had received the lot in question  
 7 by the investigating officer. I did not always  
 8 divulge that information unless requested  
 9 specifically by the individual and never  
 10 provided any information in writing as they were  
 11 advised that they would need to send a subpoena  
 12 to our legal department if they needed  
 13 documentation of any kind."  
 14 Do you see that?  
 15 A. Yes.  
 16 Q. So what was your reason for not  
 17 divulging that information to law enforcement  
 18 unless specifically requested?  
 19 A. I don't remember the specifics of this  
 20 situation back in 2010, but it's usually policy  
 21 we don't discuss that information over the  
 22 phone.  
 23 Q. But if you had -- if the law  
 24 enforcement agent had specifically requested it,

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1 you would have divulged it over the phone, is  
 2 that right?  
 3 A. I may have pointed them in the right  
 4 direction to help with their investigation.  
 5 Q. And is there any reason that you would  
 6 require them to specifically request the  
 7 information before you would help them with the  
 8 investigation?  
 9 MR. O'CONNOR: Object to form.  
 10 A. Because we didn't want to assume what  
 11 they were looking for, and they didn't always  
 12 give us details, so we didn't assume what they  
 13 were looking for. So unless they specifically  
 14 asked me, I didn't provide the information.  
 15 BY MR. GOTTO:  
 16 Q. Was it your intention to cooperate  
 17 with law enforcement when you received inquiries  
 18 of this nature?  
 19 A. To the best of my ability, yes.  
 20 Q. And did you feel that requiring them  
 21 to specifically request the information before  
 22 you would divulge it was cooperating to the best  
 23 of your ability?  
 24 A. Yes.

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1 Q. You could have informed them of the  
 2 information without the specific request,  
 3 though, right?  
 4 MR. O'CONNOR: Objection to form.  
 5 A. If they didn't request it, I didn't  
 6 know what they were looking for, and I didn't  
 7 assume or presume to know what they were looking  
 8 for.  
 9 BY MR. GOTTO:  
 10 Q. Did Ms. Harper -- we see her e-mail in  
 11 response. Apart from her e-mail, did she ever  
 12 communicate with you with respect to your  
 13 practice of how to respond to law enforcement  
 14 inquiries as you describe it in that first  
 15 paragraph?  
 16 A. I don't understand the question.  
 17 Q. Sure.  
 18 You describe in your first paragraph  
 19 of your June 17th e-mail how you handled  
 20 inquiries from law enforcement, and this point  
 21 of not divulging information unless specifically  
 22 requested. Did Ms. Harper ever respond to you  
 23 with respect to that practice to say either it  
 24 was the right way to handle the inquiries or to

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1 suggest some other way to handle them?  
 2 MR. O'CONNOR: Objection to form.  
 3 A. So those were conversations with our  
 4 legal department.  
 5 MR. O'CONNOR: And of course, I  
 6 instruct the witness not to answer to the extent  
 7 it gets into conversations with legal.  
 8 BY MR. GOTTO:  
 9 Q. Okay. So -- and you can just answer  
 10 this yes or no. Apart from conversations with  
 11 legal counsel, did you ever have any  
 12 conversations with Ms. Harper on this topic of  
 13 how you responded to inquiries from law  
 14 enforcement of the type you describe in this  
 15 paragraph?  
 16 A. Not that I remember.  
 17 Q. And again, apart from conversations  
 18 with counsel, did you have discussions with  
 19 anyone else at Mallinckrodt with respect to how  
 20 you responded to law enforcement inquiries as  
 21 you describe in this paragraph?  
 22 A. With the security director at this  
 23 time.  
 24 Q. And who was that?

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<p>1 A. Bill Ratliff.</p> <p>2 Q. And what can you recall of that</p> <p>3 conversation?</p> <p>4 A. Basically as I previously stated, we</p> <p>5 don't assume what they're looking for, we don't</p> <p>6 know the facts of their case, and we answer the</p> <p>7 questions to the best of our ability. But we</p> <p>8 don't always know who we're talking to over the</p> <p>9 phone, so if they are looking for detailed</p> <p>10 information or want documentation they have to</p> <p>11 send a subpoena so that it goes through the</p> <p>12 proper channels.</p> <p>13 Q. Okay. And did Mr. Ratliff give you</p> <p>14 any feedback as far as that approach, either</p> <p>15 confirming it or suggesting a change?</p> <p>16 A. I was cautioned not to give out</p> <p>17 information over the phone because we don't know</p> <p>18 who we're talking to over the phone.</p> <p>19 Q. The practice that you described</p> <p>20 regarding when you would give information, when</p> <p>21 you would require a subpoena, was there a</p> <p>22 written policy in place at Mallinckrodt to that</p> <p>23 effect?</p> <p>24 A. I don't believe there's a written</p>	<p>1 uncovered, do you recall?</p> <p>2 A. The customer called us and said they</p> <p>3 had received C2 product.</p> <p>4 Q. Okay. And who was Brenda Rehkop?</p> <p>5 R-E-H-K-O-P.</p> <p>6 A. Customer service rep.</p> <p>7 Q. Were you able to determine how it came</p> <p>8 to be that the product was shipped to Masters</p> <p>9 after they had been put on hold?</p> <p>10 A. It was a timing thing. There was an</p> <p>11 order picked and packed in the warehouse already</p> <p>12 at the time that customer service was notified</p> <p>13 to put the orders on hold.</p> <p>14 Q. So on the first page of the exhibit,</p> <p>15 your e-mail dated July 13, 2011, you say "I</p> <p>16 completely understand and will not disclose.</p> <p>17 It's impossible to manage so many accounts</p> <p>18 manually due to these circumstances that are</p> <p>19 beyond our control."</p> <p>20 What were you referring to there in</p> <p>21 terms of being impossible to manage so many</p> <p>22 accounts manually?</p> <p>23 A. So it was an assumption on my part</p> <p>24 that they have multiple accounts in which</p>
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<p>1 policy. I believe it was through verbal</p> <p>2 training.</p> <p>3 Q. And who gave you that verbal training?</p> <p>4 A. Our legal department.</p> <p>5 Q. Okay. You can set that aside.</p> <p>6 (Whereupon, Mallinckrodt-Spaulding-31</p> <p>7 was marked for identification.)</p> <p>8 BY MR. GOTTO:</p> <p>9 Q. Exhibit 31 is a multi-page e-mail</p> <p>10 thread bearing Bates MNK-T1_0005424123. These</p> <p>11 are e-mails from July of 2011. There were</p> <p>12 several e-mails here. I have a couple of</p> <p>13 questions for you really on the first page.</p> <p>14 (Witness reviewing document.)</p> <p>15 A. Okay.</p> <p>16 Q. Do you recognize those e-mails?</p> <p>17 A. I vaguely recall them, yes.</p> <p>18 Q. Okay. What do you recall about them?</p> <p>19 A. This was in the time that we were</p> <p>20 stopping shipments to Masters and putting their</p> <p>21 account on hold, and there was a system error in</p> <p>22 which some material that was shipped was not</p> <p>23 supposed to be.</p> <p>24 Q. Okay. And how was that error</p>	<p>1 they're releasing orders daily for clinics,</p> <p>2 because at this time we shipped clinic orders</p> <p>3 same day. They had orders that were coming in.</p> <p>4 This was at the time that there was action going</p> <p>5 on, I believe, with KeySource and Masters at the</p> <p>6 same time, and we were trying to stop orders in</p> <p>7 transit because the ISO had been issued. And</p> <p>8 there was just multiple balls in the air</p> <p>9 juggling all at one time, and this one order</p> <p>10 fell through the cracks.</p> <p>11 Q. When you say that the order fell</p> <p>12 through the cracks, were you able to ascertain</p> <p>13 who had authorized the shipment to be made?</p> <p>14 A. Yes.</p> <p>15 Q. And who was that?</p> <p>16 A. It was a CSR who released the order.</p> <p>17 Q. And who was it?</p> <p>18 A. Cheryl Nelson.</p> <p>19 Q. Were there any changes made to</p> <p>20 practices or policies to assure that this sort</p> <p>21 of mistake wouldn't happen in the future?</p> <p>22 A. Yes.</p> <p>23 Q. What were they?</p> <p>24 A. So instead of the customer service rep</p>

<p style="text-align: right;">Page 238</p> <p>1 changing -- being able to change the credit          2 limit to prevent it from shipping, that now has          3 to be done by a separate department that manages          4 the customer accounts, taking that          5 responsibility off from the CSRs.          6 Q. Do you recall in any of the          7 DEA-sponsored seminars or Buzzeo programs that          8 you attended discussions regarding the          9 involvement of either customer service personnel          10 or sales personnel in the suspicious order          11 monitoring program?          12 MR. O'CONNOR: Objection to form.          13 A. I recall at a Buzzeo conference them          14 saying that it's not in the best interest of a          15 company for finance people to be involved in SOM          16 perspective to eliminate that optic of          17 impropriety.          18 BY MR. GOTTO:          19 Q. Okay. And do you recall any similar          20 observation you made with respect to involvement          21 of sales personnel in SOM?          22 A. No, because we have to rely on sales          23 personnel to provide us information sometimes.          24 Q. You can set that aside.</p>	<p style="text-align: right;">Page 240</p> <p>1 correct?          2 A. Yes, based on this e-mail.          3 Q. So had Mallinckrodt requested of          4 Cedardale that Cedardale refrain from selling to          5 specific identified pharmacies?          6 A. Based on this e-mail, yes.          7 Q. Okay. You don't independently recall          8 that?          9 A. No.          10 Q. Do you recall there being other          11 situations in which Mallinckrodt made requests          12 of its distributors not to sell to particular          13 indirect customers?          14 A. No.          15 Q. And then Mr. Picciano goes on to          16 provide information regarding Cedardale's SOM          17 program, correct?          18 A. Yes.          19 Q. And this appears to be before you          20 conducted the on-site audit, correct?          21 A. Yes.          22 Q. And in your March 23rd e-mail to          23 Ms. Harper, you say you reviewed the attached          24 documents, "continue to believe Cedardale needs</p>
<p style="text-align: right;">Page 239</p> <p>1 (Whereupon, Mallinckrodt-Spaulding-32          2 was marked for identification.)          3 BY MR. GOTTO:          4 Q. Exhibit 32 is a two-page e-mail thread          5 with the numbers MNK-T1_0000282686, e-mails from          6 March of 2011 concerning suspicious order          7 monitoring. Tell me if you recognize those          8 e-mails.          9 (Witness reviewing document.)          10 A. Yes.          11 Q. So the earliest e-mail in the thread          12 is from a David Picciano to Karen Harper.          13 And do you know who Mr. Picciano know          14 was?          15 A. Yes.          16 Q. Who was he?          17 A. He's the director of regulatory          18 compliance for Cedardale.          19 Q. Okay. And he says this in his e-mail,          20 "Cedardale Distributors...is willing to comply          21 with Covidien's request that we refrain from          22 selling Mallinckrodt's 15-milligram and          23 30-milligram oxycodone tablets to the Florida          24 based pharmacies listed on Attachment 1,"</p>	<p style="text-align: right;">Page 241</p> <p>1 more work around their SOM program."          2 So was your e-mail prior to the          3 on-site audit?          4 A. My e-mail, no. My e-mail was after          5 their audit in which he sent me those SOPs.          6 Because when we were there for the audit we          7 advised him that he might want to look at making          8 them more robust.          9 Q. Okay. So the SOPs are -- is that          10 what's referenced in -- are you making reference          11 to what's in the November 15th e-mail?          12 A. No. So if you look at the subject          13 line, you can tell it changes with the March,          14 2011 e-mail from my e-mail to Karen with a CC to          15 Rich.          16 Q. Okay.          17 A. And that's where I'm sending her the          18 SOPs that David Picciano has sent to me.          19 Q. I see. Okay.          20 And at that point you concluded that          21 their SOM program was still insufficient,          22 correct?          23 A. Still weak, yes.          24 Q. All right. You can set that aside.</p>



<p style="text-align: right;">Page 242</p> <p>1 (Whereupon, Mallinckrodt-Spaulding-33  2 was marked for identification.)  3 BY MR. GOTTO:  4 Q. Exhibit 33 is a one-page document,  5 MNK-T1_0000290887, additional e-mails relating  6 to the Cedardale audit, and these are in January  7 of 2011.  8 A. Yes.  9 MR. O'CONNOR: Counsel, I apologize,  10 can we go off the record for a minute?  11 MR. GOTTO: You bet.  12 THE VIDEOGRAPHER: The time is  13 3:35 p.m., we're off the record.  14 (Off the record discussion.)  15 THE VIDEOGRAPHER: The time is  16 3:36 p.m., and we're on the record.  17 (Whereupon, Mallinckrodt-Spaulding-34  18 was marked for identification.)  19 BY MR. GOTTO:  20 Q. Exhibit 34 is a one-page e-mail  21 thread, MNK-T1_0003044340. Take a moment to  22 look at those e-mails, if you would, and tell me  23 if you recognize them.  24 (Witness reviewing document.)</p>	<p style="text-align: right;">Page 244</p> <p>1 unfamiliar of the inner workings of quota, and  2 we explained how St. Louis plant receives  3 manufacturing quota, we receive procurement  4 quota, and that our quota ultimately turns into  5 product that we send to the market.  6 BY MR. GOTTO:  7 Q. Okay. So how did the suspicious order  8 monitoring program relate to that?  9 A. So I can't assume what DEA wanted to  10 know or how it ties in. We could just explain  11 our program.  12 Q. Okay. I'm just -- since this is your  13 e-mail, I'm just wondering when you said  14 "provide information on the SOM and how it  15 relates to quota," was there information that  16 comes to your mind as being -- that you provided  17 in response to that request?  18 A. I don't remember specific information  19 that was provided or if there was a  20 presentation, only that we explained the quota  21 process and we reviewed our suspicious order  22 monitoring program, and that we can't ship  23 anything to the market that we haven't been  24 granted quota for.</p>
<p style="text-align: right;">Page 243</p> <p>1 A. Okay.  2 Q. Do you recognize those e-mails?  3 A. I don't remember them, no.  4 Q. Okay. Who is Kenneth Yamashita?  5 A. He was a site director at the time.  6 Q. Okay. In your June 20th e-mail you  7 say "I briefed Clay on the situation on your  8 absence."  9 Who was Clay?  10 A. Clay Wagner was the plant controller,  11 so he was the designee when Ken Yamashita was  12 out of the office.  13 Q. The last sentence of that paragraph  14 says "We have been asked to provide information  15 on our Suspicious Order Monitoring Program and  16 how it relates to quota and ties in with  17 St. Louis plant manufacturing quota."  18 What was that information? How did  19 the SOM program relate to quota and tie in with  20 the St. Louis plant manufacturing quota?  21 MR. O'CONNOR: Objection to form.  22 A. So we explained to DEA, we hosted them  23 on-site, and we explained to them the quota  24 process at a high level, because DI White was</p>	<p style="text-align: right;">Page 245</p> <p>1 Q. Okay. So Mr. Yamashita then responds  2 to you "Great. Thanks for the update. Did you  3 get the impression now that if our quota  4 justification and suspicious order monitoring  5 program is good, we will get the quota or at  6 least some portion?"  7 Do you remember what your answer to  8 that was?  9 A. No.  10 Q. So Mr. Yamashita seems to be at least  11 questioning whether -- or inquiring into whether  12 the quality of the suspicious order monitoring  13 program could have an effect on the DEA's  14 decision as to quota to grant, is that how you  15 understand his e-mail?  16 MR. O'CONNOR: Objection to form.  17 A. I don't know what his thoughts were at  18 that time.  19 BY MR. GOTTO:  20 Q. Okay. Was it your belief at this  21 time, or has it been at any time, that the DEA  22 would be more likely to grant a quota request if  23 it were persuaded that the suspicious order  24 monitoring program was of high quality?</p>

<p style="text-align: right;">Page 246</p> <p>1 A. No. Ken Yamashita was new to the  2 plant at that time, he was probably just  3 learning about how it works and what the  4 expectations are.  5 Q. Okay.  6 (Whereupon, Mallinckrodt-Spaulding-35  7 was marked for identification.)  8 BY MR. GOTTO:  9 Q. Exhibit 35 is a multi-page e-mail  10 thread, MNK-T1_0000283719. These are e-mails  11 from 2011 regarding quota requests. If you'd  12 take a look at them for just a moment, please.  13 My particular question is on the e-mail that's  14 on the second page.  15 (Witness reviewing document.)  16 A. Okay.  17 Q. Do you recognize these e-mails?  18 A. Vaguely.  19 Q. Okay. So the e-mail at the bottom of  20 the first page onto the second page, is that  21 from Frank Sapienza?  22 A. No, so that's the bottom -- I'm sorry,  23 bottom e-mail of the first page?  24 Q. Yes, the one that starts "Hi Karen."</p>	<p style="text-align: right;">Page 248</p> <p>1 Q. Do you know if it's a group at the  2 DEA?  3 A. I don't.  4 (Whereupon, Mallinckrodt-Spaulding-36  5 was marked for identification.)  6 BY MR. GOTTO:  7 Q. Exhibit 36 is a two-page document  8 beginning at Bates MNK-T1_0006055924. It  9 appears to be an e-mail exchange in August of  10 2012 concerning safety stock. Tell me if you  11 recognize those e-mails, please.  12 (Witness reviewing document.)  13 A. Okay.  14 Q. Do you recognize those e-mails?  15 A. No.  16 Q. Okay. There is -- the e-mail in the  17 middle of the first page from you to Kevin  18 Hewlett -- first of all, who is Kevin Hewlett?  19 A. He was the corporate planning manager  20 at the time.  21 Q. Okay. You make reference to a formula  22 that was used in favor of the most recent  23 several requests. Is the formula the formula  24 that's in the attachment?</p>
<p style="text-align: right;">Page 247</p> <p>1 A. Yes. What we referred to earlier in  2 which they have to go for additional signatures.  3 Q. Okay. And then on the second page,  4 the material in the middle that starts with "One  5 of our industry colleagues forwarded" --  6 A. Yes.  7 Q. -- who is it that was sending that  8 e-mail?  9 A. I have no idea. Oh, sending it,  10 that's Karen.  11 Q. Okay. And so this is information that  12 Ms. Harper received from someone else in the  13 industry in June of 2011, correct?  14 A. That's my understanding of this, yes.  15 Q. Okay. And so in this -- on these  16 eight points, the fifth point is "External  17 review 3: The suspicious order monitoring group  18 reviews and makes sure our material is not being  19 used to complete suspicious orders."  20 Do you have an understanding as to who  21 the suspicious order monitoring group is that's  22 referred to in that item?  23 A. No, because this is pulled from  24 somebody else in industry.</p>	<p style="text-align: right;">Page 249</p> <p>1 A. Yes.  2 Q. And is this what you discussed -- you  3 testified to, I think this morning, regarding  4 quota formula?  5 A. Yes.  6 Q. So this was the formula that was used  7 back in 2012?  8 A. Yes.  9 Q. Has the formula changed since that  10 time?  11 A. No.  12 Q. Okay. You can set that aside.  13 (Whereupon, Mallinckrodt-Spaulding-37  14 was marked for identification.)  15 BY MR. GOTTO:  16 Q. Exhibit 37 is a one-page e-mail,  17 MNK-T1_0006056192. This appears to also be the  18 quota formula. Could you take a look at that  19 and confirm that for me?  20 A. Yes. Correct.  21 Q. Okay. You can set that aside.  22 (Whereupon, Mallinckrodt-Spaulding-38  23 was marked for identification.)  24 BY MR. GOTTO:</p>

<p style="text-align: right;">Page 250</p> <p>1 Q. Exhibit 38 is a multi-page e-mail          2 thread, MNK-T1_0005641401. Again, these are          3 e-mails concerning quota. And my questions for          4 you concern Ms. Johnson's e-mail at the bottom          5 of the first page.          6 A. Okay.          7 Q. She says "Yes, you have it straight.          8 Part of the difference is the formulas are in AA          9 and the quota analysis is in Salt."          10 What does that mean, AA and salt in          11 this context?          12 A. So AA is anhydrous alkaloid, and          13 that's how quota is measured by, the base          14 content. So our analysis, because we receive          15 API in its salt form isomer on the dock, our          16 analysis and what we track is all in salt form.          17 But when we have to request quota from the DEA,          18 we have to convert it back to AA, and every          19 molecule has its own conversion factor to go          20 from salt to AA.          21 Q. Okay. You can set that aside.          22 (Whereupon, Mallinckrodt-Spaulding-39          23 was marked for identification.)          24 BY MR. GOTTO:</p>	<p style="text-align: right;">Page 252</p> <p>1 And with respect to Exhibit 39, we are          2 now making a clawback request with respect to          3 that because this document is protected by the          4 attorney/client privilege as well as the work          5 product protection, and we'll be following up          6 with a letter shortly.          7 MR. GOTTO: Okay. And as to 39,          8 that's the entire document?          9 MR. O'CONNOR: That's correct.          10 MR. GOTTO: Okay. Fair enough.          11 BY MR. GOTTO:          12 Q. Ms. Spaulding, if you'd take the          13 redacted Exhibit 33 that you now have in front          14 of you, I do have a couple questions for you on          15 that. And this is Bates MNK-T1_0000290887.          16 Take a look -- it's a one-page e-mail thread.          17 Take a look at that, if you would, and tell me          18 if you recognize it.          19 A. Yes.          20 Q. And so your e-mail to Mr. Nikolaus on          21 January 14 of 2011 indicates that you "just got          22 off a Suspicious Order Monitoring Steering          23 Committee conference call discussing the SOM          24 audits. I sent Karen the preliminary report</p>
<p style="text-align: right;">Page 251</p> <p>1 Q. Exhibit 39 is a two-page e-mail          2 beginning at Bates MNK-T1_0007729523, appears to          3 be an e-mail that you sent to Donald Lohman,          4 L-O-H-M-A-N.          5 Who is Mr. Lohman?          6 A. He's our legal counsel.          7 Q. Okay.          8 MR. O'CONNOR: Counsel, maybe now is a          9 good time for a break.          10 MR. GOTTO: Sounds like it might be.          11 THE VIDEOGRAPHER: The time is          12 3:49 p.m., and we're off the record.          13 (Whereupon, a recess was taken.)          14 THE VIDEOGRAPHER: The time is          15 4:04 p.m., and we're on the record.          16 MR. GOTTO: Counsel?          17 MR. O'CONNOR: All right. Counsel,          18 thank you for that break.          19 Just to clarify what's transpired          20 here, with respect to Exhibit 33, that document          21 was clawed back pursuant to a November 27, 2018          22 letter, so we have just gone ahead during the          23 break and replaced the unredacted, clawed back          24 version with the redacted version.</p>	<p style="text-align: right;">Page 253</p> <p>1 awaiting any comments from you. Basically the          2 committee has decided to release Masters and          3 KeySource to resume shipping Oxy 15-milligram          4 and 30-milligram when we come out of backorder,          5 but has determined based on our audit that          6 Cedardale does not have a robust enough system          7 in place to resume shipping C2s to them."          8 Correct?          9 A. Yes.          10 Q. Do you recall that decision by the          11 committee?          12 A. Based on this e-mail, yes.          13 Q. So you don't have an independent          14 recollection of what the basis was for the          15 decision to release Masters and KeySource at          16 this point?          17 A. No.          18 Q. Okay. You can set that aside.          19 (Whereupon, Mallinckrodt-Spaulding-40          20 was marked for identification.)          21 BY MR. GOTTO:          22 Q. Exhibit 40 is a two-page document,          23 MNK-T1_0006442504, appears to be an e-mail from          24 you to Richard Nikolaus dated July 17th of 2008</p>

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1 attaching a letter to Denise Jordan at DEA.  
 2 Take a moment and tell me if you recognize that  
 3 e-mail and the attachment.  
 4 A. I don't recognize the e-mail, but it  
 5 is one of my letters.  
 6 Q. Okay. So in your e-mail you say  
 7 "Rich, Take a look when you get a chance and let  
 8 me know what you think. I'm running out of BS  
 9 to put in these letters, especially this one."  
 10 And then the letter is to Denise  
 11 Jordan at the DEA.  
 12 Who was Denise Jordan?  
 13 A. She was the diversion investigator  
 14 responsible for our site at that time.  
 15 Q. And so your letter is in response to  
 16 an inquiry you received from her, is that right?  
 17 A. No, this is attached filing a 106. So  
 18 we had a loss in transit, and this is  
 19 notification to DEA of the details regarding the  
 20 loss in transit.  
 21 Q. Okay. So judging from your cover  
 22 e-mail where you say "I'm running out of BS to  
 23 put in these letters," was there something in  
 24 the Denise Jordan letter that you were referring

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1 to in particular by that phrase?  
 2 A. No, I was -- it was a poor choice of  
 3 words basically. I was running out of  
 4 explanations to explain why FedEx had lost  
 5 another package.  
 6 Q. And is that because there had been a  
 7 large number of incidents like that?  
 8 A. I don't know how many there had been  
 9 during this specific time frame.  
 10 Q. So were there other communications --  
 11 when you say "to put in these letters," by  
 12 "these letters" you mean letters to the DEA  
 13 dealing with a loss incident?  
 14 A. Yes. Because FedEx would give us very  
 15 little information, so we were, you know, trying  
 16 to be factual in what we put to DEA, but DEA  
 17 would sometimes push back and say, well, what is  
 18 FedEx doing about it? And we'd go to FedEx and  
 19 say, what are you doing about it? And they'd  
 20 say, that's an internal investigation, we can't  
 21 disclose an internal investigation, we can't  
 22 disclose an internal investigation. So as -- we  
 23 were caught between a rock and a hard place.  
 24 Q. Okay. You can put that aside.

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1 (Whereupon, Mallinckrodt-Spaulding-41  
 2 was marked for identification.)  
 3 BY MR. GOTTO:  
 4 Q. Exhibit 41 is a copy of the  
 5 Administrative Memorandum of Agreement between  
 6 Mallinckrodt and the DEA from 2017. Take a look  
 7 at that document, if you would. First tell me  
 8 if you've seen it before.  
 9 A. Yes.  
 10 Q. Okay. Are you familiar with it?  
 11 A. Yes.  
 12 Q. When did you first become aware that  
 13 the DEA was formally investigating Mallinckrodt?  
 14 A. During the 2013 inspection.  
 15 Q. Okay. Did you receive copies of  
 16 subpoenas that were issued by DEA in 2011 and  
 17 2012?  
 18 A. I've received copies of subpoenas. I  
 19 don't remember if they were 2011 or 2012.  
 20 Q. Okay. But you recall in 2013 becoming  
 21 aware of the investigation?  
 22 A. Yes, because of the audit that was  
 23 conducted in March and April of 2013.  
 24 Q. Okay. And what was it about that

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1 audit that made you become aware of the  
 2 investigation?  
 3 A. They had 15 to 16 agents and were  
 4 there for 6 weeks, which was unprecedented to  
 5 any other audit that had ever been done previous  
 6 to that.  
 7 Q. So in previous audits, approximately  
 8 how many people would be there and for  
 9 approximately how long?  
 10 A. Two to four days and less than a  
 11 week -- sorry. Two to four people, and there  
 12 less than a week.  
 13 Q. Okay. Did you provide any sworn  
 14 testimony to DEA as part of your investigation?  
 15 A. Sworn testimony, no, I don't believe  
 16 so.  
 17 Q. Okay. No affidavits, anything like  
 18 that?  
 19 A. There was an inspection report that  
 20 was signed. There was legal documents provided.  
 21 But I don't recall signing anything.  
 22 Q. Okay. You do recall receiving a  
 23 subpoena from the DEA at some point, correct?  
 24 A. Yes, I received them frequently for



<p style="text-align: right;">Page 258</p> <p>1 shipping verifications.</p> <p>2 Q. Okay. And do you recall receiving a</p> <p>3 subpoena that you understood to be in connection</p> <p>4 with the DEA's investigation of Mallinckrodt?</p> <p>5 A. No.</p> <p>6 Q. Were you aware of anyone else at</p> <p>7 Mallinckrodt giving a deposition or sworn</p> <p>8 statement to the DEA in connection with its</p> <p>9 investigation of Mallinckrodt?</p> <p>10 A. Not that I was aware of, no.</p> <p>11 Q. Did you have any involvement in the</p> <p>12 discussions between Mallinckrodt and DEA that</p> <p>13 led up to the memorandum of agreement?</p> <p>14 A. Yes.</p> <p>15 Q. What discussions were you involved in?</p> <p>16 A. So we were -- we went to Albany DEA</p> <p>17 and met with them to review the mass balance</p> <p>18 records after they had taken copies of all of</p> <p>19 the batch records that were part of the audit.</p> <p>20 There was follow-up questions from DEA regarding</p> <p>21 the reports that we had provided, so those were</p> <p>22 all answered. That was my direct involvement</p> <p>23 with DEA.</p> <p>24 Q. What are the mass balance records?</p>	<p style="text-align: right;">Page 260</p> <p>1 Hobart site making sure that anything we agreed</p> <p>2 to was feasible to manage and manageable.</p> <p>3 Q. Okay. On the first page of the</p> <p>4 administrative memorandum of agreement, there</p> <p>5 are a number of numbered paragraphs under</p> <p>6 "Background."</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And do you recall reviewing those</p> <p>10 paragraphs when you reviewed a draft of this</p> <p>11 document?</p> <p>12 A. Yes.</p> <p>13 Q. And was there any inaccuracy in any of</p> <p>14 those paragraphs that you can recall from your</p> <p>15 review?</p> <p>16 A. Not that I recall.</p> <p>17 Q. In Paragraph 2 it indicates that "From</p> <p>18 January 1, 2008, through September 30, 2011,</p> <p>19 there was an epidemic increase in diversion of</p> <p>20 the controlled substance oxycodone, largely out</p> <p>21 of the State of Florida."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. Was that a circumstance you were aware</p>
<p style="text-align: right;">Page 259</p> <p>1 A. So that's how DEA does an audit of a</p> <p>2 manufacturer. They basically take your</p> <p>3 year-ending inventory, add in all your</p> <p>4 acquisitions, and subtract out all your</p> <p>5 dispositions.</p> <p>6 Q. And the review that you participated</p> <p>7 in with the Albany DEA, what was the focus of</p> <p>8 that review?</p> <p>9 A. They audit three major molecules and</p> <p>10 all products produced within 14 months of</p> <p>11 oxycodone, hydrocodone, and Methadone.</p> <p>12 Q. Did that review disclose any</p> <p>13 discrepancies?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. I don't know. DEA never provides us</p> <p>16 reports, so I don't know what they came up with.</p> <p>17 BY MR. GOTTO:</p> <p>18 Q. Did you review a draft of the</p> <p>19 administrative memorandum of agreement before it</p> <p>20 was signed?</p> <p>21 A. Yes.</p> <p>22 Q. And what was the purpose of your</p> <p>23 review?</p> <p>24 A. Because I was the key person at the</p>	<p style="text-align: right;">Page 261</p> <p>1 of during the time period January 1 of '08</p> <p>2 through September 30th of 2011?</p> <p>3 A. I don't know if I was aware of it at</p> <p>4 that time or not.</p> <p>5 Q. Paragraph 3 indicates that "The United</p> <p>6 States alleges that Mallinckrodt, a manufacturer</p> <p>7 and distributor of oxycodone, knew about the</p> <p>8 diversion and sold excessive amounts of the most</p> <p>9 highly abused forms of oxycodone, 30-milligram</p> <p>10 and 15-milligram tablets, placing them into a</p> <p>11 stream of commerce that would result in</p> <p>12 diversion."</p> <p>13 Did you believe that that allegation</p> <p>14 was accurate when you reviewed a draft of this</p> <p>15 document?</p> <p>16 A. No.</p> <p>17 Q. What parts of it do you think were</p> <p>18 inaccurate?</p> <p>19 A. That we knowingly sold excessive</p> <p>20 amounts.</p> <p>21 Q. Okay. Paragraph 4 indicates that</p> <p>22 "Mallinckrodt had a responsibility to maintain</p> <p>23 effective controls against diversion, including</p> <p>24 a requirement that it review and monitor these</p>



<p>Page 262</p> <p>1 sales and report suspicious orders to DEA." 2 Did you believe that was accurate when 3 you reviewed it? 4 A. Yes. 5 Q. Paragraph 5, the last sentence states 6 "Furthermore, the United States alleges that 7 Mallinckrodt never notified the DEA of the 8 suspicious orders in violation of the CSA." 9 Did you believe that statement was -- 10 or that that allegation was accurate when you 11 reviewed a draft of this document? 12 A. No. 13 Q. If you'd turn to Paragraph 3 on Page 2 14 of the document, Paragraph 3(a) states that 15 "With respect to its distribution of oxycodone 16 and hydrocodone products, Mallinckrodt's alleged 17 failure to distribute these controlled 18 substances in a manner authorized by its 19 registration and Mallinckrodt's alleged failure 20 to operate an effective suspicious order 21 monitoring system and to report suspicious 22 orders to the DEA when discovered as required by 23 and in violation of 21 CFR Section 1301.74(b)." 24 Did you believe that the allegations</p>	<p>Page 264</p> <p>1 conduct adequate due diligence of its customers? 2 A. Yes. 3 Q. And do you believe -- under Roman 4 Numeral ii, do you believe that Mallinckrodt 5 detected and reported to the DEA orders of 6 unusual size and frequency? 7 A. What is an order of unusual size and 8 frequency? I mean, yes, we did the best with 9 the information we had. 10 Q. You understood that there was a 11 regulatory obligation to report orders of 12 unusual size and frequency, correct? 13 A. Yes. 14 Q. The next paragraph, "detect and report 15 to the DEA orders deviating substantially from 16 normal patterns." 17 Again, you understood that there was a 18 regulatory requirement to detect and report such 19 orders, correct? 20 A. Yes. 21 Q. And do you believe Mallinckrodt did 22 so? 23 A. Yes. 24 Q. Paragraph iv, "use 'chargeback'</p>
<p>Page 263</p> <p>1 described in that sentence were accurate when 2 you reviewed a draft of this document? 3 A. The alleged allegations, yes. 4 Q. You understand -- 5 A. Wait a minute. I'm sorry, I don't 6 understand. 7 Q. You understood it was accurate that 8 those allegations were made. My question is, 9 did you believe that the underlying allegations 10 were accurate? 11 A. No. 12 Q. And in what regard did you believe 13 they were not accurate? 14 A. We were reporting any orders that we 15 deemed to be truly suspicious, and I don't 16 believe that we failed to report any suspicious 17 orders. And although there's allegations and we 18 settled with the MOA, we didn't admit any 19 wrongdoing. 20 Q. And under paragraph A, there's 21 specific -- in the Roman Numeral numbered 22 paragraphs, number "i. conduct adequate due 23 diligence of its customers." 24 Do you believe that Mallinckrodt did</p>	<p>Page 265</p> <p>1 information from its distributors to evaluate 2 suspicious orders." 3 Prior to October of 2010, Mallinckrodt 4 did not use chargeback data as part of its SOM 5 program, correct? 6 A. No, it's not part of the regulations. 7 Q. And Roman Numeral v, "take sufficient 8 action to prevent recurrence of diversion by 9 downstream customers after receiving concrete 10 information of diversion of Mallinckrodt product 11 by those downstream customers." 12 Do you believe that Mallinckrodt was 13 under an obligation to take action to prevent 14 recurrence of diversion in these circumstances? 15 MR. O'CONNOR: Objection to form. 16 A. Not under the regulations, but as part 17 of our MOA, yes. 18 BY MR. GOTTO: 19 Q. Paragraph B has a series of 20 allegations regarding the Hobart facility, 21 correct? 22 A. Yes. 23 Q. And these are matters that you have 24 some personal familiarity with, correct?</p>

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1 A. Yes.

2 Q. And so paragraph "i. failure to take

3 actual weights of controlled substances at all

4 stages of the manufacturing process."

5 Did you feel that was an accurate

6 allegation?

7 A. Yes.

8 Q. And what was done to rectify that

9 situation going forward?

10 A. We immediately at the -- this was

11 discovered during the 2013 audit, and so we

12 immediately updated the records that didn't have

13 complete weights, complete physical inventory of

14 the entire site was taken to make sure we had a

15 complete and accurate inventory, and we changed

16 our receiving process to do a check-weigh on all

17 API coming in, not just a seal verification and

18 label verification.

19 Q. Okay. Paragraph ii, Roman ii, "use of

20 a 'target' tablet weight for purposes of

21 reconciling batch records and determining the

22 number of units of finished form manufactured

23 even though the actual average weight of the

24 tablets in any specific batch sometimes deviated

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1 from the target weight."

2 Did you believe the allegation

3 described in B(ii) was an accurate allegation?

4 A. Yes.

5 Q. And what was done to rectify that

6 going forward?

7 A. Again, immediately during the 2013

8 audit before this MOA, we changed our procedures

9 to calculate an actual weight per lot for each

10 batch produced, and that actual weight per batch

11 is now what's used in reconciliation purposes.

12 Q. Okay. And B(iii) related to

13 "commingling of dust collector waste and

14 assignment of dust losses."

15 Did you feel that was an accurate

16 allegation when it was made?

17 A. No.

18 Q. What part of it did you think was not

19 accurate?

20 A. Without confirming how much dust was

21 actually attributable to any specific batch.

22 Q. Do you know why the DEA alleged that

23 lack of confirmation?

24 MR. O'CONNOR: Objection to form.

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1 A. Because of the way that the dust

2 collectors operate and are designed, there is

3 challenges with being able to account for any

4 specific batch, but it's not a result of not

5 trying to determine how much went into each

6 batch.

7 BY MR. GOTTO:

8 Q. How about Roman Number iv, "failure to

9 check-weigh controlled substances received into

10 the facility," was that an accurate allegation?

11 A. Yes.

12 Q. What was done to rectify that?

13 A. As mentioned before, the check-weigh

14 of all procedures -- of all controlled

15 substances coming into the facility.

16 Q. And Roman Numeral v, "failure to

17 maintain accurate records of substances

18 transferred from the manufacturing process to

19 Mallinckrodt's analytical laboratories," did you

20 think that was an accurate allegation?

21 A. Yes.

22 Q. And what was done to rectify that?

23 A. So there was a gap in our record

24 receiving documents within the laboratories, and

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1 again during the 2013 audit, it was -- DEA had

2 detected that, and we immediately updated our

3 documents to have traceability of all samples

4 coming into the lab regardless of their

5 controlled substance schedule.

6 Q. Okay. And Roman Numeral vi, "failure

7 to include substances held in certain

8 vaults/storage as part of the biannual

9 inventory, and records provided for vaults

10 containing discrepancies with respect to weight,

11 missing substances, incorrect lots/batch

12 numbers, and incorrect or incomplete drug

13 names." Did you believe that was an accurate

14 allegation when it was made?

15 A. Yes.

16 Q. And what was done to rectify that?

17 A. That was part of the complete physical

18 inventory that was taken that same time period

19 of counting and documenting every single

20 controlled substance in the facility.

21 Q. So the various allegations under

22 paragraph B that you've indicated you believed

23 were accurate allegations when they were made,

24 were those circumstances that came into

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1 existence during 2013?  
2 A. Came, like had just started?  
3 Q. Yes.  
4 A. No.  
5 Q. Okay. Do you have any idea when they  
6 did start?  
7 A. No, that's just when they were  
8 detected.  
9 Q. And what caused them to be detected?  
10 A. Part of the audit that the DEA  
11 conducted.  
12 Q. And do you know what was different in  
13 the 2013 audit that gave rise to that detection  
14 that hadn't caused these circumstances to be  
15 detected previously?  
16 A. In the 2000 DEA -- 2013 DEA audit,  
17 there was more investigators there, and they  
18 were going through the batch records in greater  
19 detail than they had in any previous audit.  
20 Q. Okay. Paragraph 4 states it is not an  
21 admission of liability, however, Mallinckrodt  
22 agrees that at certain times certain aspects of  
23 Mallinckrodt's system to monitor and detect  
24 suspicious orders did not meet the standards

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1 outlined in letters from the DEA deputy  
2 administrator from September and December of  
3 2006 and 2007 respectively.  
4 Do you see that?  
5 A. Yes.  
6 Q. And do you believe that's true, that  
7 certain aspects of the SOM program in place at  
8 Mallinckrodt prior to January 1, 2012 did not  
9 meet standards outlined in those letters?  
10 A. Do I personally?  
11 Q. Yes.  
12 A. No, I believe they did.  
13 Q. Do you know why Mallinckrodt agreed  
14 that the SOM did not meet certain of those  
15 standards?  
16 A. I do not.  
17 Q. Did you have any discussions with  
18 anyone at Mallinckrodt prior to the time this  
19 memorandum of agreement was executed with  
20 respect to that point?  
21 A. I remember having discussions. I  
22 don't know if it was part of the memorandum of  
23 agreement that we were doing the best we could  
24 with what we had and the direction we had been

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1 given.  
2 Q. Did you ever receive any performance  
3 evaluation that -- well, strike that.  
4 In any of your performance evaluations  
5 that you received at Mallinckrodt, was the  
6 subject of the suspicious order monitoring  
7 program one of the items on which you were  
8 evaluated?  
9 A. Yes.  
10 Q. And what evaluations did you receive  
11 in that regard?  
12 A. I was always meeting expectations.  
13 Q. And who was it who performed your  
14 evaluations?  
15 A. My manager.  
16 Q. Ms. Harper?  
17 A. Yes.  
18 Q. You were familiar with the DEA letters  
19 from September of '06 and December of '07 that  
20 are referred to in Paragraph 4, correct?  
21 A. Yes.  
22 Q. So if, in fact, aspects of  
23 Mallinckrodt's SOM program did not meet the  
24 standards outlined in those letters, that

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1 failure would have indicated, at least to some  
2 extent, a personal failure on your regard -- on  
3 your part with respect to the SOM program,  
4 right?  
5 MR. O'CONNOR: Objection to form.  
6 A. I don't think I understand. Are you  
7 saying that because we admitted that our program  
8 wasn't robust I wasn't doing my job?  
9 BY MR. GOTTO:  
10 Q. Well, let me put it a little  
11 differently.  
12 During the period prior to January 1  
13 of 2012, did you attempt to cause the SOM  
14 program at Mallinckrodt to be in compliance with  
15 the standards outlined in the DEA letters of  
16 September of '06 and December of '07?  
17 A. I believe I did, yes.  
18 Q. Okay. And so if, in fact, the program  
19 was not in compliance with those standards, then  
20 that would have meant that you failed to achieve  
21 your objective in that regard, correct?  
22 MR. O'CONNOR: Object to form.  
23 A. I disagree with that.  
24 BY MR. GOTTO:

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1 Q. You disagree with whether the program  
2 met the standards, right?

3 A. No, I disagree with whether I was  
4 doing what was expected of me and met the intent  
5 of the letters based on the information and the  
6 direction that we have. DEA gives very little  
7 guidance around what is an unusual order, what  
8 is a suspicious order, so we have to interpret  
9 that the best that we can, and I feel that I've  
10 done that.

11 MR. GOTTO: Okay. Why don't we go off  
12 the record.

13 THE VIDEOGRAPHER: The time is  
14 4:34 p.m., and we're off the record.  
15 (Whereupon, a recess was taken.)

16 THE VIDEOGRAPHER: The time is  
17 4:45 p.m., and we're on the record.

18 EXAMINATION

19 BY MR. GESTEL:

20 Q. Good evening, Ms. Spaulding.

21 MR. GESTEL: Before I begin, I'll just  
22 launch what has become our standard objection  
23 without going into the whole basis for that, if  
24 you'll let me. I assume that you'll --

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1 MR. O'CONNOR: I'll offer our standard  
2 objection to the objection.

3 MR. GESTEL: All right. Thank you.

4 BY MR. GESTEL:

5 Q. Ms. Spaulding, my name is Ben Gestel.  
6 I represent a group of plaintiffs in the State  
7 of Tennessee that are in a slightly different  
8 lawsuit than the lawsuit that Mr. Gotto was  
9 asking you questions about this morning.

10 I'll begin by asking you, have you  
11 reviewed the complaint in any of the Tennessee  
12 cases?

13 A. No.

14 Q. I'm going to also sort of back up and  
15 do a couple of preliminary things.

16 Where do you live? What is your  
17 residential address?

18 A. [REDACTED]

19 [REDACTED]

20 Q. And how long have you lived there?

21 A. 12 years.

22 Q. And who lives there with you?

23 A. Currently alone.

24 Q. And then do you have any plans to move

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1 any time soon?

2 A. Not that I foresee.

3 Q. And then, if this was covered this  
4 morning I apologize, but can you do a -- provide  
5 some -- a little bit of your educational  
6 background?

7 Did you graduate from college?

8 A. Again, I have an associate from BYU in  
9 computer information systems.

10 Q. When you say BYU, is that Brigham and  
11 Young University?

12 A. Yes, the Idaho campus.

13 Q. And how long ago did you receive that  
14 degree?

15 A. 1990.

16 Q. And were you living in Idaho at the  
17 time?

18 A. While I attended college. No, I lived  
19 in New Jersey, went to college in Idaho, and  
20 came back to New Jersey.

21 Q. Got it. Thank you very much.

22 And what is your current title at  
23 Mallinckrodt?

24 A. Controlled substances compliance

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1 manager.

2 Q. And in that role do you have  
3 supervisory authority over any employees?

4 A. Yes, I have two employees on my team.

5 Q. Who is directly reporting to you?

6 A. Carrie Johnson and Rachelle Rogers.

7 Q. And if I'm understanding the testimony  
8 earlier, are you continuing to directly report  
9 to Karen Harper?

10 A. I am.

11 Q. In your work with Mallinckrodt, did  
12 you have occasion to travel to the State of  
13 Tennessee?

14 A. I have attended a conference in  
15 Tennessee.

16 Q. Do you remember what conference that  
17 was?

18 A. NADDI conference in Nashville.

19 Q. Do you remember what year that was?

20 A. Not the exact. It's within the past  
21 five years.

22 Q. Apart from attending that NADDI  
23 conference in Nashville, do you recall ever  
24 travelling to the State of Tennessee for your



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1 work for Mallinckrodt?

2 A. No.

3 Q. So you don't ever recall travelling to

4 a distributor's facility in Tennessee to do an

5 audit?

6 A. I stand corrected. I have travelled

7 to Memphis in my role at Mallinckrodt to FedEx.

8 And I've been to a distributor -- no, they're

9 not in Tennessee, sorry. Just FedEx in Memphis,

10 Tennessee.

11 Q. And do you recall when it was you went

12 to FedEx?

13 A. Not exactly. I've been there three or

14 four times.

15 Q. When was the most recent trip that you

16 were there?

17 A. It's been many years.

18 Q. And can you just provide a general

19 overview of what you were doing at that FedEx

20 facility?

21 A. We were doing a collaboration visit.

22 They gave us a tour of the facility. We were

23 conducting an audit because we had had some

24 losses in transit with FedEx, and reviewing

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1 their security procedures and how they handle

2 Mallinckrodt freight when it goes through the

3 hub.

4 Q. And was this before the transition

5 over to the FedEx Express service that you

6 talked about this morning?

7 A. It was after.

8 Q. It was after that.

9 And you said "we went." Do you recall

10 who went with you?

11 A. Security managers, Rich Nikolaus.

12 Q. Anybody else attend on that trip?

13 A. No, not that I can recall.

14 Q. As you sit there today, do you have

15 any understanding of opioid prescription rates

16 in the State of Tennessee?

17 A. No.

18 MR. O'CONNOR: Objection to form.

19 BY MR. GESTEL:

20 Q. I think you testified earlier that you

21 believe that there's a current opioid epidemic

22 going on in this country, is that correct?

23 MR. O'CONNOR: Objection.

24 A. I'm aware of it.

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1 BY MR. GESTEL:

2 Q. And are you aware that epidemic is

3 particularly acute in some parts of the country

4 compared to other parts of the country?

5 MR. O'CONNOR: Objection to form.

6 A. Yes.

7 BY MR. GESTEL:

8 Q. Do you believe that Tennessee has been

9 particularly hard-hit by the opioid crisis?

10 MR. O'CONNOR: Objection to form.

11 A. I don't know how significant or hit

12 any one state is over another.

13 BY MR. GESTEL:

14 Q. Sure.

15 But do you understand or do you

16 believe that Tennessee has -- is one part of

17 those country -- one part of this country that

18 has been particularly hit by the opioid

19 epidemic?

20 MR. O'CONNOR: Objection.

21 A. I'm aware that Tennessee has concerns.

22 I don't know the specific facts to know whether

23 it was one of the highest or not or more so than

24 any other state.

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1 BY MR. GESTEL:

2 Q. Do you recall during your time with

3 Mallinckrodt ever discussing any specific pill

4 mill operations in the State of Tennessee?

5 MR. O'CONNOR: Objection to form.

6 A. Nothing specific, no.

7 BY MR. GESTEL:

8 Q. Have you ever reviewed IMS Health data

9 regarding the rates of prescribing of opioids

10 related to the State of Tennessee?

11 A. No.

12 Q. Have you ever heard of Interstate 75

13 being described as the "Oxy Express"?

14 A. Yes.

15 Q. About when did you first hear that

16 term?

17 A. Several years ago. I don't remember

18 exactly when.

19 Q. And I don't mean to test your

20 knowledge of American geography, but are you

21 aware that Interstate 75 runs through the State

22 of Tennessee?

23 A. At a high level, yes.

24 Q. In your role as manager of controlled



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1 substances, did you interact with law  
2 enforcement officials in the State of Tennessee?  
3 A. I interact with law enforcement  
4 officials. I don't remember specifically if any  
5 of them have been from Tennessee. They could  
6 have, but I don't know specifically.  
7 Q. Did you have occasion to ever just  
8 have a conversation with a police officer from  
9 Morristown, Tennessee? Does that ring a bell in  
10 your mind at all?  
11 A. I believe the security director had a  
12 conversation with someone from Morristown,  
13 Morrisville.  
14 Q. But you weren't involved in that  
15 conversation, to the best of your recollection?  
16 A. No, not directly.  
17 Q. How did you learn about it indirectly?  
18 A. The security director asked me for  
19 shipping information, that he had been contacted  
20 by somebody from Morrisville, Tennessee.  
21 Q. And then why would he contact you  
22 about that information, if you know?  
23 A. Because I was at the distribution  
24 center and could run the reports to know what --

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1 where we shipped our orders to.  
2 Q. And then did you provide him the  
3 report that he asked for?  
4 A. Yes.  
5 Q. And then did you follow up with him at  
6 all after providing that report about the status  
7 of that Morristown investigation?  
8 A. No.  
9 Q. Have you ever asked any law  
10 enforcement official about prescription opioid  
11 division -- I'm sorry, strike that.  
12 Have you ever asked any law  
13 enforcement official where prescription opioid  
14 diversion was most prevalent?  
15 A. No, not that I can recall.  
16 Q. During your time with Mallinckrodt,  
17 have you ever had occasion to run reports  
18 detailing the percentage of oxycodone sales for  
19 Mallinckrodt's distributors in certain states?  
20 A. Can you say that again?  
21 Q. Sure.  
22 During your time with Mallinckrodt,  
23 have you had occasion to run reports detailing  
24 the percentage of Oxy sales for Mallinckrodt's

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1 distributors in certain states?  
2 A. I have not, no.  
3 Q. I'm going to hand you a document that  
4 we'll mark as Exhibit 42.  
5 (Whereupon, Mallinckrodt-Spaulding-42  
6 was marked for identification.)  
7 MR. GESTEL: (Handing). Sorry, that  
8 was a little -- like Tom Brady over here.  
9 BY MR. GESTEL:  
10 Q. I hand you a document that's been  
11 marked as Exhibit 42. I'll represent to you  
12 that the first page is a cover page carrying the  
13 Bates label of this Excel spreadsheet that was  
14 sent to us, and it has some what's called  
15 metadata showing that it was last modified on  
16 September 2, 2011. The reason why we do that,  
17 ma'am, is that the spreadsheet was produced to  
18 us in native format so the Bates numbers don't  
19 appear, but that's the Bates number of this  
20 document.  
21 And if you flip to the first page, in  
22 the upper left-hand corner there is in column  
23 A1, it says "Oxy's percent of sales by state per  
24 distributor versus sales in all US by district,"

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1 I assume.  
2 Do you see that?  
3 A. Yes.  
4 Q. Have you ever seen this document  
5 before, ma'am?  
6 A. I don't remember if I have or have  
7 not.  
8 Q. Do you ever recall doing any training  
9 on this document, where you might have trained  
10 people to run these reports?  
11 A. No.  
12 Q. Do you see that the state listed here  
13 is Florida?  
14 A. Yes.  
15 Q. And then flip to the next page. Do  
16 you see that the state listed there is Texas?  
17 A. Yes.  
18 Q. And flip to the next page. Do you see  
19 that the state listed there is Ohio?  
20 A. Yes.  
21 Q. And flip to the next page. Do you see  
22 that the state listed there is Kentucky?  
23 A. Yes.  
24 Q. And then flip to the next page. And

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1 do you see there that the state listed there is  
2 Tennessee?  
3 A. Yes.  
4 Q. And none of this is -- you don't  
5 believe you've ever seen this document before?  
6 A. I don't remember it.  
7 Q. And then flip to the next page. And  
8 there's the State of Georgia. Do you see that?  
9 A. Yes.  
10 Q. And then if you flip to the next page,  
11 there's a graph titled "Percent of Oxycodone  
12 Sales in Florida."  
13 Do you see that?  
14 A. Mm-hmm.  
15 Q. Do you recall ever seeing a graph like  
16 this in your work with Mallinckrodt?  
17 A. No, I don't remember.  
18 Q. And do you remember why, if at all, in  
19 2011 Mallinckrodt might have become interested  
20 in tracking oxycodone sales to the states listed  
21 in this spreadsheet?  
22 A. Only due to DEA activities around that  
23 time period.  
24 Q. And if you wanted to have a chart like

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1 this made for you, it sounds like you don't  
2 recall running these types of reports, who would  
3 you go to within Mallinckrodt in 2011, if you  
4 can recall, to run a report like this?  
5 A. Oxy sales by state by distributor. It  
6 could have been in our finance department, or it  
7 would go to our marketing department.  
8 Q. And who in those departments would you  
9 direct an inquiry to?  
10 A. Whoever was the head of the department  
11 at the time.  
12 Q. Would that have been Jen Buist?  
13 A. No. Jen Buist would have gotten it  
14 from one of those departments.  
15 Q. Would it have been Jen Terp?  
16 A. Could have been. I don't know for  
17 sure.  
18 Q. You can set that aside. Thank you  
19 very much.  
20 (Whereupon, Mallinckrodt-Spaulding-43  
21 was marked for identification.)  
22 BY MR. GESTEL:  
23 Q. I'm going to hand you a document that  
24 we'll mark as Exhibit 43.

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1 MS HOSMER: Do you have a Bates number  
2 for us, please?  
3 MR. GESTEL: Sure.  
4 MS HOSMER: Thank you.  
5 BY MR. GESTEL:  
6 Q. This is an e-mail carrying Bates label  
7 MNK-T1\_0007898862. And then do you see that  
8 this is an e-mail dated November 26, 2013 from  
9 Jennifer Buist to you carrying a subject "KVK  
10 Heat Maps"? Did I read that correctly?  
11 A. Yes.  
12 Q. Do you recall this e-mail?  
13 A. Vaguely.  
14 Q. And then, let me put a clean copy up.  
15 And the first -- or the last e-mail in that  
16 chain says "These may be discussed during our  
17 staff meeting."  
18 Do you see that?  
19 A. Yes.  
20 Q. And then a couple e-mails down is an  
21 e-mail from Julie Milford to Jacob Longenecker  
22 with Jen Terp and Jennifer Buist copied.  
23 Do you see that?  
24 A. Yes.

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1 Q. And the body of that e-mail says "Hi  
2 Jake, Attached are the heat maps with  
3 Mallinckrodt data. I also added a section on  
4 per capita usage to negate any effects or  
5 questions around population sizes. Similar  
6 patterns still exist that suggest relatively  
7 high usage in the Pacific Northwest, especially  
8 for the 5-milligram tablet. In general, there  
9 are still high rates in the KY, WV, and  
10 Tennessee area and in Florida."  
11 Did I read that correctly?  
12 A. Yes.  
13 Q. And attached to this e-mail chain is  
14 this referenced heat maps, and I think it's just  
15 a PowerPoint presentation carrying the title  
16 "Volume Heat Maps."  
17 Do you see that?  
18 A. Yes.  
19 Q. Do you recall ever running these heat  
20 maps while you were employed at Mallinckrodt?  
21 A. No, I didn't run them.  
22 Q. Do you recall this spread -- or this  
23 PowerPoint presentation as you sit here today?  
24 A. Now that I'm looking at it, I vaguely

<p style="text-align: right;">Page 290</p> <p>1 remember it, yes.</p> <p>2 Q. And then if you flip to the first page</p> <p>3 of the PowerPoint presentation, it says "MNK</p> <p>4 geographical patterns are similar to the rest of</p> <p>5 the market."</p> <p>6 Did I read that correctly?</p> <p>7 A. You said the first page?</p> <p>8 Q. The first page of the PowerPoint.</p> <p>9 A. Yes.</p> <p>10 Q. And then there's two maps. There's a</p> <p>11 map carrying the title of "All Strengths -</p> <p>12 Mallinckrodt."</p> <p>13 Do you see that?</p> <p>14 A. "All Strengths - Mallinckrodt," yes.</p> <p>15 Q. And then the second map is "All</p> <p>16 Strengths - Other Manufacturers."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And then it appears that based on the</p> <p>20 legend here at the bottom that the deeper purple</p> <p>21 you get in an area, the more Oxy prescriptions</p> <p>22 in that area. Is that your understanding of</p> <p>23 this heat map?</p> <p>24 A. Well, it's saying "All Strengths," so</p>	<p style="text-align: right;">Page 292</p> <p>1 it says the source is IMS, LRx, Xponent.</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. And it's apparently from July, 2012 to</p> <p>5 June, 2013?</p> <p>6 A. Yes.</p> <p>7 Q. Do you know what the IMS, LRx, Xponent</p> <p>8 references?</p> <p>9 A. No, I do not.</p> <p>10 Q. Do you believe that that could be a</p> <p>11 reference to IMS Health data?</p> <p>12 A. Reasonably.</p> <p>13 Q. Are you familiar with IMS Health data?</p> <p>14 A. At a very, very high level.</p> <p>15 Q. Do you use that at all in suspicious</p> <p>16 order monitoring program at Mallinckrodt?</p> <p>17 A. I do not, no.</p> <p>18 Q. Do you know of anybody within the</p> <p>19 suspicious order monitoring program at</p> <p>20 Mallinckrodt who uses IMS Health data?</p> <p>21 A. Not currently, no.</p> <p>22 Q. Well, was it ever used, to the best of</p> <p>23 your knowledge?</p> <p>24 A. So I know at one point in time this</p>
<p style="text-align: right;">Page 291</p> <p>1 not just oxycodone.</p> <p>2 Q. Okay. But regardless, as you get more</p> <p>3 purple, you see more -- that's more units going</p> <p>4 into that geographic territory, right?</p> <p>5 A. Based on the legend.</p> <p>6 Q. And then if you look here in the area</p> <p>7 of the country that is Tennessee, you'll see</p> <p>8 that it's -- do you see that it's purple in the</p> <p>9 areas around the State of Tennessee?</p> <p>10 A. Yes, roughly.</p> <p>11 Q. And then also on the Other</p> <p>12 Manufacturers map, the State of Tennessee is</p> <p>13 kind of more purple than other areas around it.</p> <p>14 Do you see that?</p> <p>15 A. I wouldn't say it's more purple than</p> <p>16 other areas around it, but I see it.</p> <p>17 Q. But you would agree with me that</p> <p>18 that's a -- the State of Tennessee is purple in</p> <p>19 this graph, correct?</p> <p>20 A. In which one, the Other Manufacturers</p> <p>21 or the Mallinckrodt one?</p> <p>22 Q. The Other Manufacturers.</p> <p>23 A. Yes.</p> <p>24 Q. And then do you see here at the bottom</p>	<p style="text-align: right;">Page 293</p> <p>1 group may have had access to IMS data in which</p> <p>2 Jen Buist, who was the SOM auditor analyst at</p> <p>3 the time, may have reached out to her for</p> <p>4 information, but I don't know that and I can't</p> <p>5 speak on her behalf.</p> <p>6 Q. And when you say "this group," what do</p> <p>7 you mean?</p> <p>8 A. The commercial marketing. I don't</p> <p>9 even know who Ms. Julie Milford is, but her</p> <p>10 title says she's global business insights and</p> <p>11 forecasting, commercial analytics.</p> <p>12 Q. And you're getting that from the cover</p> <p>13 of this -- the cover e-mails?</p> <p>14 A. Yes. I don't know who she is.</p> <p>15 Q. If you'll flip back, there's a very</p> <p>16 similar map to the one we just went through</p> <p>17 carrying the labels of "30-milligram." It's</p> <p>18 about halfway back, I apologize. These</p> <p>19 PowerPoint presentations aren't numbered.</p> <p>20 There's a 30-milligram chart.</p> <p>21 A. Yes.</p> <p>22 Q. And then do you see that this</p> <p>23 particular chart carries the title "Mallinckrodt</p> <p>24 and other manufacturers have very similar</p>

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1 geographical dispensing patterns"? Did I read  
2 that correctly?  
3 A. "Have very similar geographical  
4 dispensing patterns," yes.  
5 Q. And then once again we see a map with  
6 the legend that the more purple an area is, the  
7 more 30-milligram Mallinckrodt extended units  
8 have been sent into that area.  
9 Do you see that?  
10 A. Based on the map, yes.  
11 Q. And then do you see the State of  
12 Tennessee is purple once again?  
13 A. Yes.  
14 Q. If you flip to the next page, there's  
15 a -- it carries the title of "Per Capita Heat  
16 Maps."  
17 Do you see that?  
18 A. Yes.  
19 Q. And then there are similar maps to the  
20 one that we just went through. The first one  
21 listed after that cover page is the one carrying  
22 the title "The coasts have more per capita usage  
23 than the midwest."  
24 Do you see that?

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1 A. Yes.  
2 Q. And then again there's another map  
3 showing per capita Oxy usage, and it appears  
4 that the greener that you get in this map the  
5 more per capita usage you see.  
6 Do you see that?  
7 A. Based on the map, yes.  
8 Q. And then on the "All Strengths -  
9 Mallinckrodt," you'll see that Tennessee, and  
10 particularly East Tennessee, is green.  
11 Do you see that?  
12 A. I don't know exactly where Tennessee  
13 starts and ends, but --  
14 Q. Well, if you go over to the "All  
15 Strengths - Other Manufacturers," the outline of  
16 the State of Tennessee is a little bit more  
17 prevalent there in the southeast portion of the  
18 country.  
19 Do you see that?  
20 A. Yes.  
21 Q. And then if you -- the area,  
22 especially the eastern portion of that area is  
23 also lit up on the Mallinckrodt All Strengths  
24 map, correct?

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1 A. The All Strengths - Other  
2 Manufacturers, yes.  
3 Q. And then also on the All Strengths -  
4 Mallinckrodt map, the eastern portion of that  
5 region is also green.  
6 Do you see that?  
7 A. No, because I see darker green spots  
8 all throughout Tennessee.  
9 Q. I see.  
10 So you would agree with me that the  
11 State of Tennessee is green in the All Strengths  
12 - Mallinckrodt map?  
13 A. It's a light shade of green, yes.  
14 Q. And then once again if you'll flip  
15 back to the 30-milligram page, a very similar  
16 heat map showing the -- carrying the title "Per  
17 capita usage of the Oxy 30 tablet is lowest in  
18 the midwest." Did I read that correctly?  
19 A. Can you say that again, please?  
20 Q. Sure.  
21 The title of the 30-milligram slide is  
22 that "Per capita usage of the Oxy 30 tablet is  
23 lowest in the midwest."  
24 Did I read that correctly?

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1 A. I went the wrong way.  
2 Q. I think it's the second-to-last, or  
3 might be the very last page.  
4 A. Last page. Got it, yes.  
5 Q. And then once again on the  
6 Mallinckrodt 30-milligram page, we see that  
7 Tennessee is green, suggesting once again larger  
8 per capita usage.  
9 Do you see that?  
10 A. I can't tell where Tennessee starts  
11 and ends, but I see that there's green on the  
12 map.  
13 Q. Sure.  
14 And then also over here on the  
15 30-Milligram - Other Manufacturers, you also see  
16 in the area of the State of Tennessee green,  
17 suggesting greater per capita Oxy 30 usage in  
18 the State of Tennessee, right?  
19 A. Based on these maps, yes.  
20 Q. And once again, not to belabor the  
21 point, but apparently the source of the per  
22 capita map is also this IMS, LRx, Xponent from  
23 July 2012 to June 2013.  
24 Do you see that?

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1 A. I see it. I don't know what it is.  
2 Q. Sure.  
3 Do you recall using these heat maps at  
4 all in the suspicious order monitoring program?  
5 A. I do not, no.  
6 Q. But you don't have a specific  
7 recollection as to whether or not the suspicious  
8 order monitoring program was generating these  
9 heat maps as part of its suspicious order  
10 monitoring program?  
11 A. Correct. Jen Buist was the analyst at  
12 the time responsible.  
13 Q. And do you know who Jen reported to?  
14 A. She started out reporting to Gail  
15 Tetzlaff, director of government reporting.  
16 Q. Okay. And then at some point did that  
17 change?  
18 A. Yes. Then she reported to Don Lohman  
19 in legal.  
20 (Whereupon, Mallinckrodt-Spaulding-44  
21 was marked for identification.)  
22 BY MR. GESTEL:  
23 Q. Same rules apply, by the way, if you  
24 need a break by all means, just say so and we

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1 can take a break.  
2 A. Thank you.  
3 Q. I can assure you I will be much  
4 shorter in my examination than Mr. Gotto was  
5 this morning, but...  
6 I'll hand you a document that we'll  
7 mark as Exhibit 44. I do this once a deposition  
8 where I accidentally mark my copy, so just give  
9 me one second and let me flip this over. I  
10 should learn my lesson and that should be the  
11 last one that I mismark.  
12 This is an e-mail sent on June 29,  
13 2012 from you to Karen Harper carrying the  
14 subject line "DEA Albany/New York City Meeting  
15 notes on SOM/Quota."  
16 Did I read that correctly?  
17 A. Yes.  
18 Q. And you ask Karen Harper to "review  
19 and make edits/comments as you feel appropriate.  
20 Please advise when I may publish to Ken."  
21 Did I read that correctly?  
22 A. Yes.  
23 Q. Do you recall what you mean by this  
24 "publish to Ken" comment?

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1 A. Sent to Ken Yamashita, the site  
2 director.  
3 Q. And he was the site director for what  
4 site?  
5 A. Hobart.  
6 Q. For Hobart?  
7 A. Yes.  
8 Q. And then if you flip over, this e-mail  
9 attaches this Word document carrying the title  
10 "Notes from Hobart Meeting with DEA Albany/NYC  
11 on SOM and Quota, 6/26/12."  
12 Do you see that?  
13 A. Yes.  
14 Q. Do you recall this meeting with the  
15 DEA in June of 2012?  
16 A. To be honest, no, I don't.  
17 Q. And that's all right. But you see  
18 that you -- in the Mallinckrodt attendees you're  
19 listed there at the bottom, Eileen Spaulding?  
20 A. Yes.  
21 Q. Any reason to doubt that you were  
22 there?  
23 A. No, no. I'm sure I was there. I just  
24 don't remember it.

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1 Q. And then apparently there was some  
2 question/answer between Mallinckrodt  
3 representatives and the DEA, and I want to  
4 direct your attention to the bottom of that  
5 first page of the Word document. There's a  
6 question there about "How long does it take to  
7 process lines?" Do you see that question?  
8 A. Yes.  
9 Q. And then the answer apparently given  
10 was "Reports are run daily at 9:00 a.m. and 3:00  
11 Central. The average time is 10 to 15 minutes  
12 to review and process each line that has gone on  
13 hold."  
14 Did I read that correctly?  
15 A. Yes.  
16 Q. Is that suggesting that processing  
17 lines, these are the orders that have been  
18 flagged by the suspicious order monitoring  
19 algorithm as needing further investigation?  
20 A. Yes.  
21 Q. And then the average time to process  
22 those were 10 to 15 minutes to review?  
23 A. Each line.  
24 Q. For each line?



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1 A. For each order, yes.  
2 Q. Okay. Flip to the next page. Top of  
3 the page, the question "When you say 195 lines  
4 filed, what does it mean?" And then the answer  
5 is "It means that the line has hit the algorithm  
6 and requires review and/or investigation."  
7 Did I read that correctly?  
8 A. Yes.  
9 Q. Does that suggest that there's 195  
10 lines that are hitting the algorithm?  
11 A. It could.  
12 Q. And is that, do you know, or do you  
13 recall, is that 195 lines a month, a week, a  
14 day?  
15 A. I don't know the time period that Don  
16 was speaking to.  
17 Q. And you don't recall any specifically  
18 from this meeting?  
19 A. No. I mean, as I testified earlier, I  
20 remember reviewing our SOM program, but I don't  
21 remember specifics of the meeting.  
22 Q. Sure.  
23 And then the next question there is  
24 "How many orders have been deemed suspicious?"

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1 Do you see that?  
2 A. Yes.  
3 Q. And then the answer is "None, it was  
4 explained that this updated SOM program went  
5 into place on 3/1/2012 and no orders have been  
6 determined to be suspicious since that date."  
7 Did I read that correctly?  
8 A. Correct.  
9 Q. Is that consistent with your  
10 recollection that there was no suspicious order  
11 reported on the updated SOM program since it  
12 went into place on March 1st of 2012?  
13 A. Between March 1st of 2012 and the date  
14 of this meeting on June 26th of 2012, correct.  
15 Q. And then does that -- taking that with  
16 the previous question, does that suggest to you  
17 that the 195 lines that were flagged were in  
18 that period between June 1st -- I'm sorry,  
19 March 1st, 2012 and the date of this meeting of  
20 June 26, 2012?  
21 MR. O'CONNOR: Object to form.  
22 A. I don't know. I wouldn't want to  
23 guess that that is.  
24 BY MR. GESTEL:

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1 Q. You can set that aside.  
2 (Whereupon, Mallinckrodt-Spaulding-45  
3 was marked for identification.)  
4 BY MR. GESTEL:  
5 Q. I'm going to hand you what's been  
6 marked as Exhibit 45. Sorry, I'm somehow down a  
7 copy.  
8 Do you see that this is a document  
9 Bates stamped MNK-T1\_0006967775, and it's  
10 carrying the title "CSC Steering Committee  
11 Meeting Notes," December 12, 2012.  
12 Do you see that?  
13 A. Yes.  
14 Q. And you are on the suspicious order  
15 monitoring steering committee at that time,  
16 correct?  
17 A. Yes.  
18 Q. And you see that there's a reference  
19 to introducing John?  
20 A. Yes.  
21 Q. Do you recall who that was?  
22 A. John Gillies.  
23 Q. And was he just coming on board at  
24 this time?

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1 A. Yes.  
2 Q. Flip to the second page. There's some  
3 bullet items there, and it says, third one down,  
4 it says "We also dropped out," and I think  
5 that's a typo, it should be "our multiplier from  
6 ■ to ■."  
7 Do you see that?  
8 A. Yes.  
9 Q. So does that suggest to you that in  
10 December of 2012 that the suspicious order  
11 monitoring algorithm threshold was lowered from  
12 ■ to ■?  
13 A. Yes.  
14 Q. And then I believe that you testified  
15 earlier that eventually that was also further  
16 reduced down to ■?  
17 MR. O'CONNOR: Objection to form.  
18 A. I don't remember stating that. I  
19 don't know that it's ■. I know it went from 2  
20 to 3, we spoke about that earlier, but I don't  
21 remember that it went from ■ down to ■.  
22 BY MR. GESTEL:  
23 Q. So is the multiplier currently ■?  
24 A. Yes.

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1 Q. And do you believe that that's been  
 2 the case from December of 2012 to the present?  
 3 A. Based on my knowledge, yes.  
 4 Q. And then it has a description there,  
 5 "we multiply the 18 month average of orders on a  
 6 per customer, per SKU basis and multiply that  
 7 amount by [REDACTED] to get the level at which orders  
 8 will trip the volume flag that month. We do the  
 9 same for number of orders."  
 10 Did I read that correctly?  
 11 A. Yes.  
 12 Q. And is that a description of how the  
 13 algorithm functionally works?  
 14 A. One component of it.  
 15 Q. And so is it safe to say that once you  
 16 move the [REDACTED] multiplier, if an order was within  
 17 [REDACTED] times the 18-month moving average that that  
 18 order would not be flagged and would be  
 19 processed and shipped?  
 20 MR. O'CONNOR: Objection to form.  
 21 A. If it did not? Can you repeat that?  
 22 BY MR. GESTEL:  
 23 Q. Sure.  
 24 Is it safe to say that once you move

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1 the [REDACTED] multiplier, if an order was within [REDACTED]  
 2 [REDACTED] the 18-month moving average  
 3 that order would not be flagged and would be  
 4 processed and shipped?  
 5 A. If it was less than [REDACTED], yes, that's  
 6 correct.  
 7 Q. And that would be the same for the  
 8 number of orders, right?  
 9 A. For this frequency, order frequency,  
 10 yes.  
 11 Q. And then -- and is that how the  
 12 algorithm continues to operate today?  
 13 A. Yes.  
 14 Q. For both volume of order and for the  
 15 number of orders?  
 16 A. Yes.  
 17 Q. And then if you flip -- continuing on  
 18 that page, it ends with this reference to "Jen  
 19 Buist Statistics."  
 20 Do you see that?  
 21 A. Yes.  
 22 Q. And then there's a reference to a tier  
 23 1 and a tier 2.  
 24 Do you see that?

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1 A. Yes.  
 2 Q. What is tier 1 and tier 2?  
 3 A. Tier 1 is the top three major  
 4 distributors for Oxy 15-milligram and Oxy  
 5 30-milligram. So if there -- it's a  
 6 multi-layered system. So tier 1 looks at Oxy 15  
 7 and Oxy 30s for the big three, and if the order  
 8 hits the threshold amount, then it will go on a  
 9 tier 1 hold. Tier 2 is based on all orders  
 10 being reviewed by an 18-month history.  
 11 Q. Okay. And am I understanding your  
 12 testimony correctly that only the big three  
 13 distributors would be in the tier 1?  
 14 A. Yes.  
 15 Q. And just for the record, who are the  
 16 big three?  
 17 A. McKesson, AmerisourceBergen, and  
 18 Cardinal.  
 19 Q. And then tier 2, am I understanding  
 20 your testimony correctly that that's essentially  
 21 everybody else?  
 22 A. That's everybody including the  
 23 distributors, but it's based on an 18-month --  
 24 including the big three distributors for all

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1 products, but it's based on the 18-month  
 2 history. So that's where it's referring to the  
 3 multiplier above.  
 4 Q. Got it.  
 5 And then do you see that there's two  
 6 columns there of "Order Lines Processed" and  
 7 "Order Lines Failed"? Do you see that?  
 8 A. Yes.  
 9 Q. And in tier 1, just take March of  
 10 2012, there's 124 order lines processed and 56  
 11 order lines failed.  
 12 Do you see that?  
 13 A. Mm-hmm.  
 14 Q. So does that mean that in March of  
 15 2012, for tier 1 orders there were 124 of them?  
 16 A. There were 124 orders processed. 56  
 17 went on hold.  
 18 Q. And that means that it flagged the  
 19 algorithm?  
 20 A. Yes.  
 21 Q. Do you recall what was going on in  
 22 March of 2012 to suggest that high level of  
 23 flagging by the algorithm?  
 24 A. I don't. I know it's when the program

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1 started, so I don't know if there was historical  
2 data that needed to be loaded.  
3 Q. Sure.  
4 A. Or I don't remember specifically.  
5 Q. And then you see for the rest of the  
6 tier 1, that March of 2012 is an anomaly? Would  
7 you agree with me with that?  
8 A. Yes.  
9 Q. So -- and then there's less orders  
10 processed going down the line, and then  
11 correspondingly less order fails, correct?  
12 A. Correct.  
13 Q. And again, that's the number of those  
14 orders that are being flagged by the algorithm,  
15 right?  
16 A. Correct, for tier 1.  
17 Q. So if you just look at the averages  
18 here, you take an average, and it does the math  
19 for you there, 78 average orders during that  
20 time period, on average 7 monthly fails.  
21 Do you see that?  
22 A. It's 78 lines, not 78 orders.  
23 Q. Sorry. Thank you.  
24 78 lines, 7 line fails, right?

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1 A. Yes.  
2 Q. And just simple math, that suggests  
3 that 90 percent of the orders are making its way  
4 through the algorithm and being processed and  
5 shipped, right?  
6 A. If they don't hit tier 2 metrics, yes.  
7 Q. Sure.  
8 And then down on tier 2, it has the  
9 same two columns, Order Lines Processed, Order  
10 Lines Failed, right?  
11 A. Yes.  
12 Q. I don't want to belabor the point, but  
13 again, these are lines that go through the  
14 algorithm in tier 2, correct?  
15 A. Mm-hmm. Sorry, yes.  
16 Q. And then order lines failed are those  
17 that are flagged by the algorithm for additional  
18 investigation?  
19 A. Yes.  
20 Q. And then again taking the averages  
21 here, the sheet does the math for you, that's on  
22 average per month 8,436 lines on average are  
23 processed per month, correct?  
24 A. Yes.

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1 Q. And then 596 average order lines  
2 hitting the algorithm, right?  
3 A. Yes.  
4 Q. And so that's approximately, just  
5 doing the math, about 93 percent clearing the  
6 algorithm and being processed and shipped,  
7 right?  
8 A. Yeah, I don't know the math, but --  
9 not my thing.  
10 Q. And do you know, apart from sort of  
11 that March, 2012 anomaly, do these statistics  
12 hold from 2012 to the present, do you know?  
13 A. I don't, not without running reports  
14 and looking at them.  
15 Q. And I assume that, again, based on the  
16 document here, that Jen Buist must have ran  
17 these statistics?  
18 A. She did when she was in that role.  
19 Q. And it sounds like she's no longer in  
20 that role?  
21 A. Correct.  
22 Q. Who is in that role?  
23 A. Rachelle Rogers.  
24 Q. Do you know if the SOM steering

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1 committee is continuing to receive these types  
2 of reports showing how many tier 1 and tier 2  
3 order lines are being processed and hitting the  
4 algorithm?  
5 A. Not recently.  
6 Q. And then we saw in the previous  
7 document that when that investigation gets  
8 tripped, the investigation takes 10 to  
9 15 minutes, right?  
10 A. On average.  
11 Q. And is that continuing the average  
12 from 2012 to the present?  
13 A. I'd have to run reports. It's --  
14 every line is thoroughly investigated.  
15 Q. And who would you go to to run that  
16 report about how long it's taking to process the  
17 orders that are being hit by the algorithm?  
18 A. I would run it.  
19 Q. You would run the report?  
20 A. Mm-hmm.  
21 Q. How would you do it?  
22 A. We have a system. Well, let me  
23 clarify.  
24 So how long it takes to review, to

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1 review and release an order if appropriate?  
2 Q. Yes.  
3 A. So I don't know that we'd have a  
4 mechanism to know that. It's human involvement,  
5 and I have an analyst that that's what her  
6 full-time job is, and she spends a good part of  
7 her day reviewing and releasing, so I don't --  
8 we don't have a mechanism that tracks exactly  
9 how long it takes.  
10 Q. And who is that analyst?  
11 A. Rachelle Rogers currently.  
12 Q. And how long has she been in that  
13 role?  
14 A. Since December.  
15 Q. And did she take over from Jennifer  
16 Buist?  
17 A. No. She took over from Amanda Chase  
18 who was in that role for approximately a year  
19 and a half.  
20 Q. And did Amanda Chase take over the  
21 role from Jennifer Buist?  
22 A. No. Previous to Amanda Chase it was  
23 done out in corporate by Heather McKenzie, and  
24 Jen Buist was previous to Heather McKenzie.

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1 Q. Just forgive me, just give me one  
2 second because I ask a lot of questions that  
3 were already covered, and it's a lot easier for  
4 me just to look at my notes than to ask you all  
5 those questions again.  
6 As part of your role on the suspicious  
7 order monitoring steering committee, have you  
8 had a chance to review some chargeback data?  
9 A. Yes.  
10 Q. And this may have been covered  
11 earlier, but do you recall when chargeback data  
12 started being used by the suspicious order  
13 monitoring program at Mallinckrodt?  
14 A. So we reviewed some e-mails earlier  
15 today that gave a ballpark, but I don't remember  
16 exactly when.  
17 Q. And have you ever had occasion for  
18 yourself to request chargeback data?  
19 A. For myself?  
20 Q. Well, let me back up.  
21 Do you maintain the chargeback data?  
22 A. No.  
23 Q. If you needed a chargeback report run,  
24 how would you go about effectuating that?

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1 A. I would contact the finance analyst  
2 that has access to the chargeback system.  
3 Q. And who is that?  
4 A. Currently is Debbie Digby.  
5 Q. And who was it prior to Ms. Digby?  
6 A. I'm not sure who Jennifer was  
7 getting -- Jen Buist was getting them from.  
8 Q. And then have you ever had occasion to  
9 ask for chargeback data?  
10 A. Yes.  
11 Q. Any time when that request for  
12 chargeback data was refused?  
13 A. No.  
14 Q. You testified earlier that when  
15 Mallinckrodt terminated chargebacks to a  
16 pharmacy you reported this to the DEA and  
17 Mallinckrodt would inform the DEA through a  
18 letter. Do you remember that testimony?  
19 A. Yes.  
20 Q. Did Mallinckrodt maintain a copy of  
21 the letter that it sent to the DEA?  
22 A. Yes.  
23 Q. And did you send that letter?  
24 A. I send them currently. Previous to me

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1 would have been Jen Buist or Heather McKenzie.  
2 Q. Okay. And when did you start sending  
3 them?  
4 A. When SOM program transferred to Hobart  
5 back in April of 2017.  
6 Q. Okay. Thank you.  
7 I'm going to hand you a document that  
8 we marked as Exhibit 46.  
9 (Whereupon, Mallinckrodt-Spaulding-46  
10 was marked for identification.)  
11 BY MR. GESTEL:  
12 Q. And I promise you that we're near the  
13 end.  
14 You've been handed a document that's  
15 been marked as Exhibit 46. At the top of it,  
16 the title of this document is the "HZQS -  
17 Controlled Substances Compliance  
18 Responsibilities Associated with  
19 Anti-Diversion."  
20 Did I read that correctly?  
21 A. Yes.  
22 Q. And you see the revision date is  
23 March 11, 2015.  
24 Do you see that?

<p style="text-align: right;">Page 318</p> <p>1 A. Yes.</p> <p>2 Q. Do you know if this is -- continues to</p> <p>3 be the current policy?</p> <p>4 A. I don't.</p> <p>5 Q. Do you maintain the policies?</p> <p>6 A. I do not.</p> <p>7 Q. But you know that based on the record</p> <p>8 here that this was at least the portion that was</p> <p>9 in effect on March 11, 2015?</p> <p>10 A. Based on this document, yes.</p> <p>11 Q. And then if there are subsequent</p> <p>12 revisions, does the revision date gets updated</p> <p>13 and it supersedes the date of the previous</p> <p>14 revision?</p> <p>15 A. Correct, the next revision would move</p> <p>16 the March -- 03/11/2015 to supersedes date, and</p> <p>17 then become the new date.</p> <p>18 Q. Got it.</p> <p>19 I've handed you a document that we'll</p> <p>20 mark as Exhibit 47.</p> <p>21 (Whereupon, Mallinckrodt-Spaulding-47</p> <p>22 was marked for identification.)</p> <p>23 BY MR. GESTEL:</p> <p>24 Q. And this document is another SOM</p>	<p style="text-align: right;">Page 320</p> <p>1 February 19, 2015, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And then a supersedes date of a</p> <p>4 previous policy of November 14, 2013, right?</p> <p>5 A. Yes.</p> <p>6 Q. And then once again, we can assume</p> <p>7 that this is the policy that went into effect on</p> <p>8 February 19, 2015?</p> <p>9 A. Yes.</p> <p>10 Q. And then do you know if this is the</p> <p>11 current policy in effect?</p> <p>12 A. I don't.</p> <p>13 Q. But if it was revised, there would be</p> <p>14 a new revision date with the supersede date</p> <p>15 replaced with this February 19, 2015 date?</p> <p>16 A. Correct, if it had been approved.</p> <p>17 Q. That was my last policy. I hand you</p> <p>18 Exhibit Number 49.</p> <p>19 (Whereupon, Mallinckrodt-Spaulding-49</p> <p>20 was marked for identification.)</p> <p>21 BY MR. GESTEL:</p> <p>22 Q. This is an e-mail from you dated</p> <p>23 September 18, 2015 to Carrie Johnson, correct?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 319</p> <p>1 written policy. This one is entitled</p> <p>2 "Identification, Investigation, and Reports of</p> <p>3 Controlled Substances Suspicious Orders."</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. I don't want to belabor this too much,</p> <p>7 but same thing with regard to the effective date</p> <p>8 and supersede date is the same as the document</p> <p>9 that preceded this?</p> <p>10 A. Yes.</p> <p>11 Q. Do you know if this is the current</p> <p>12 in-force version of this policy?</p> <p>13 A. I don't.</p> <p>14 (Whereupon, Mallinckrodt-Spaulding-48</p> <p>15 was marked for identification.)</p> <p>16 BY MR. GESTEL:</p> <p>17 Q. You're going to notice a trend here.</p> <p>18 Exhibit 48 (handing). Once again, another SOM</p> <p>19 policy, this one entitled "Controlled Substances</p> <p>20 Compliance Responsibilities Associated with</p> <p>21 Suspicious Order Monitoring."</p> <p>22 Did I read that correctly?</p> <p>23 A. Yes.</p> <p>24 Q. And then there's a revision date of</p>	<p style="text-align: right;">Page 321</p> <p>1 Q. And it has -- carries the title</p> <p>2 "UO" -- or subject "UOR Program Review," right?</p> <p>3 A. Yes.</p> <p>4 Q. What is the UOR program?</p> <p>5 A. Unusual order reports.</p> <p>6 Q. And then if you flip back, you see</p> <p>7 that there are various attachments to this</p> <p>8 e-mail, right?</p> <p>9 A. Yes.</p> <p>10 Q. Do you recall sending this e-mail?</p> <p>11 A. I don't, no.</p> <p>12 Q. Any reason to believe that you did not</p> <p>13 send the e-mail?</p> <p>14 A. No.</p> <p>15 Q. And then if you flip back to the last</p> <p>16 page, there is a document entitled "Excluded</p> <p>17 Items within the UOR scope of JDE."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes.</p> <p>20 Q. What does that mean?</p> <p>21 A. So there's certain products that we</p> <p>22 make on behalf of other manufacturers, such as</p> <p>23 this Methylin Chewable, Methylin Oral,</p> <p>24 Tussicaps, and we do not distribute to the</p>



<p style="text-align: right;">Page 322</p> <p>1 market. So we're a contract marketing  2 organization for another manufacturer.  3 Q. Okay. And then do you see there's a  4 chart that says, two columns, "Reason" and then  5 "Definition"?  6 Do you see that?  7 A. Yes.  8 Q. And then there are three reasons  9 listed. Under the second one, there's  10 "Xartemis XR." Did I say that correctly?  11 A. Yeah, Xartemis.  12 Q. Xartemis.  13 And it says "added to table on  14 March 12, 2014. XXR deemed by SOM Team not  15 likely to be diverted into other than legitimate  16 medical channels."  17 Did I read that correctly?  18 A. Yes.  19 Q. What does that mean?  20 A. It's a branded product, and it's very  21 small volume, very expensive, so there's not a  22 lot of it moving.  23 Q. And so what does it mean that "XXR  24 deemed by SOM Team not likely to be diverted"?</p>	<p style="text-align: right;">Page 324</p> <p>1 Q. Got it. Actually that was my next  2 question.  3 So when you say removed from the list,  4 it means removed from this carveout list from  5 the suspicious order monitoring -- or I'm sorry,  6 the algorithm processing?  7 A. Correct, because they were both new  8 products that were launched, so there was no  9 history in the market to be able to measure  10 volumes against for previous orders.  11 Q. Got it.  12 So -- but then beginning on  13 January 22, 2015, these two items were then  14 added to the algorithm?  15 A. Correct, because now we had a history  16 to know what customers would be ordering of it  17 to look at.  18 Q. Got it.  19 And is that true through today, that  20 those are being ran through the algorithm?  21 A. Both products are discontinued, but  22 yes.  23 Q. Got you.  24 You went through with Mr. Gotto</p>
<p style="text-align: right;">Page 323</p> <p>1 A. It's -- XXR is the abbreviation for  2 Xartemis XR.  3 Q. Got it.  4 Does this mean that orders for this  5 particular item are not being run through the  6 algorithm?  7 A. Yes.  8 Q. And then the same thing here on the  9 next reason, "Generic Exalgo"?  10 A. Correct.  11 Q. It says it's added to the table on  12 May 15, 2014.  13 A. Added to the table, yes.  14 Q. And then "Generic Exalgo deemed by SOM  15 Team not likely to be diverted into other than  16 legitimate medical channels."  17 Did I read that correctly?  18 A. Correct.  19 Q. Does that mean that orders for the  20 generic Exalgo are also not being run through  21 the algorithm?  22 A. For both products until they were  23 removed on January 22, 2015, and then they were  24 being run.</p>	<p style="text-align: right;">Page 325</p> <p>1 some -- the memorandum of understanding entered  2 between Mallinckrodt and the United States  3 Department of Justice.  4 Do you recall that testimony?  5 A. The memorandum of agreement, yes.  6 Q. Yes.  7 Were you disciplined at all as a  8 result of the allegations by the Department of  9 Justice that led to that MOA?  10 A. No.  11 Q. Are you aware of anyone at  12 Mallinckrodt that was disciplined as a result of  13 the allegations that gave rise to the July, 2017  14 MOA with the United States Department of  15 Justice?  16 A. No.  17 Q. This must be music to your ears,  18 Ms. Spaulding, but that's all I have.  19 THE VIDEOGRAPHER: The time is  20 5:40 p.m., and we're off the record.  21 (Whereupon, a recess was taken.)  22 THE VIDEOGRAPHER: The time is  23 5:40 p.m., and we're on the record.  24 EXAMINATION</p>

<p style="text-align: right;">Page 326</p> <p>1 BY MR. O'CONNOR:</p> <p>2 Q. Ms. Spaulding, I promise to be quick.</p> <p>3 Can you please take a look at Exhibit</p> <p>4 Number 41, the memorandum of agreement? I just</p> <p>5 want to make sure we have a very clear record on</p> <p>6 this.</p> <p>7 Earlier today Mr. Gotto questioned you</p> <p>8 with regard to the Background section on Page 1</p> <p>9 of this agreement.</p> <p>10 Do you recall that testimony?</p> <p>11 A. Yes.</p> <p>12 Q. Again, just so we have a clear record,</p> <p>13 after you had a chance to review the language of</p> <p>14 that Background section with Mr. Gotto, do you</p> <p>15 agree with any of the allegations the United</p> <p>16 States was making against Mallinckrodt in these</p> <p>17 paragraphs 1 through 7?</p> <p>18 A. No.</p> <p>19 Q. Okay. And specifically you don't</p> <p>20 agree, or do you agree with the United States --</p> <p>21 strike that.</p> <p>22 Do you agree with the allegations the</p> <p>23 United States is making in paragraph 3</p> <p>24 specifically?</p>	<p style="text-align: right;">Page 328</p> <p>1 That's it.</p> <p>2 Go off the record.</p> <p>3 THE VIDEOGRAPHER: The time is</p> <p>4 5:43 p.m. This deposition has concluded, and we</p> <p>5 are off the record.</p> <p>6 (Whereupon, the deposition was</p> <p>7 concluded.)</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 327</p> <p>1 A. No.</p> <p>2 Q. And do you agree with the allegations</p> <p>3 the United States is making in paragraph 5?</p> <p>4 A. No.</p> <p>5 Q. Okay. If you could turn to Page 3,</p> <p>6 I'll direct your attention to subparagraph B, as</p> <p>7 in boy, Mr. Gotto asked you a series of</p> <p>8 questions about paragraph B. Do you recall</p> <p>9 that?</p> <p>10 A. Yes.</p> <p>11 Q. And how would you characterize the</p> <p>12 issues that are addressed in paragraph B?</p> <p>13 MR. GOTTO: Object to form.</p> <p>14 A. They are all documentation --</p> <p>15 BY MR. O'CONNOR:</p> <p>16 Q. Okay.</p> <p>17 A. -- instances.</p> <p>18 Q. Are you aware of any evidence to</p> <p>19 suggest that any of the issues described in</p> <p>20 paragraph B led to any controlled substance</p> <p>21 leaving the Hobart facility?</p> <p>22 MR. GOTTO: Object to form.</p> <p>23 A. No.</p> <p>24 MR. O'CONNOR: Okay. All right.</p>	<p style="text-align: right;">Page 329</p> <p>1 COMMONWEALTH OF MASSACHUSETTS )</p> <p>2 SUFFOLK, SS. )</p> <p>3 I, MAUREEN O'CONNOR POLLARD, RMR, CLR,</p> <p>4 and Notary Public in and for the Commonwealth of</p> <p>5 Massachusetts, do certify that on the 5th day of</p> <p>6 February, 2019, at 9:06 o'clock, the person</p> <p>7 above-named was duly sworn to testify to the</p> <p>8 truth of their knowledge, and examined, and such</p> <p>9 examination reduced to typewriting under my</p> <p>10 direction, and is a true record of the testimony</p> <p>11 given by the witness. I further certify that I</p> <p>12 am neither attorney, related or employed by any</p> <p>13 of the parties to this action, and that I am not</p> <p>14 a relative or employee of any attorney employed</p> <p>15 by the parties hereto, or financially interested</p> <p>16 in the action.</p> <p>17 In witness whereof, I have hereunto</p> <p>18 set my hand this 7th day of February, 2019.</p> <p>19</p> <p>20</p> <p>21 MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC</p> <p>22 Realtime Systems Administrator</p> <p>23 CSR #149108</p> <p>24</p>

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**INSTRUCTIONS TO WITNESS**

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2  
3 Please read your deposition over  
4 carefully and make any necessary corrections.  
5 You should state the reason in the appropriate  
6 space on the errata sheet for any corrections  
7 that are made.  
8 After doing so, please sign the  
9 errata sheet and date it. It will be attached  
10 to your deposition.  
11 It is imperative that you return  
12 the original errata sheet to the deposing  
13 attorney within thirty (30) days of receipt of  
14 the deposition transcript by you. If you fail  
15 to do so, the deposition transcript may be  
16 deemed to be accurate and may be used in court.  
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**E R R A T A**  
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**ACKNOWLEDGMENT OF DEPONENT**

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4 I, \_\_\_\_\_, do  
5 Hereby certify that I have read the foregoing  
6 pages, and that the same is a correct  
7 transcription of the answers given by me to the  
8 questions therein propounded, except for the  
9 corrections or changes in form or substance, if  
10 any, noted in the attached Errata Sheet.  
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17 Eileen Spaulding DATE  
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16 Subscribed and sworn  
17 To before me this  
18 \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.  
19 My commission expires: \_\_\_\_\_

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20 Notary Public

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**LAWYER'S NOTES**

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